

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA; STATES *
OF CALIFORNIA; CONNECTICUT; *
FLORIDA, GEORGIA; ILLINOIS; INDIANA; *
LOUISIANA; MICHIGAN; MINNESOTA; *
NEW YORK; NORTH CAROLINA; *
TENNESSEE; and, TEXAS; *
ex rel DANIEL W. CREGER, *

Plaintiffs, *

v. *

CIVIL CASE NO.: 3:20-CV-00592

PINNACLE DERMATOLOGY LLC; *
SKINCURE ONCOLOGY, LLC; CHAD A. *
ECKES; CHICAGO PACIFIC FOUNDERS; *
MARY TOLAN; DR. JOSE RIOS; DR. PAULA *
K. LAPINSKI; KERWIN J. BRANDT; *
DR. DANIEL J. LADD; KRISTA HATCHER; *
VANCE VARNIER, STEVEN B. BONNER; *
STEVEN L. SCOTT; L. PETER SMITH; *
CAPX PARTNERS; JEFFREY S. PREFFER; *
FOUNTAIN PARTNERS, D/B/A SEACOAST *
CAPITAL; TOM CARTER, JOHN VAN *
HOOSER; DERMATOLOGY SPECIALISTS *
OF FLORIDA; DERMATOLOGY *
SPECIALISTS OF GEORGIA; *
DERMATOLOGY SPECIALISTS OF *
ALABAMA; DERMATOLOGY SPECIALISTS *
OF MISSISSIPPI; DR. JON R. WARD; THE *
SKIN WELLNESS CENTER; DR. MEREDITH *
OVERHOLT; DR. KIMBERLY GRANDE; *
HEIGHTS DERMATOLOGY & *
AESTHETIC CENTER; D/B/A HEIGHTS *
DERMATOLOGY; DR. ALPESH DESAI; *
DR. TAJAS DESAI; HOLLYWOOD *
DERMATOLOGY AND COSMETIC *
SPECIALIST; DR. EDUARDO *
WEISS; DR. RONALD D. SMITH; DR. JULIAN *
O. MOORE; DR. SHOLOMO J. LANES; *
RENDON CENTER FOR DERMATOLOGY *

JUDGE: W. L. CAMPBELL, JR.
MAGISTRATE JUDGE:

JURY TRIAL DEMANDED

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QUI TAM ACTION

AND AESTHETIC MEDICINE; DR. MARTA I.*
 RENDON; DR. CHERE L. ANTHONY; *
 DR. TODD R. COVEN; DR. ANN M. REED; *
 DR. BERTHA BAUM; PARK AVENUE *
 DERMATOLOGY; DR. GEORGE *
 SCHMEIDER; DR. MARY SCHMEIDER; *
 DR. SARAH FERRER-BRUKER; SOUTHERN *
 DERMATOLOGY CENTER, PC; DR. *
 ANGELO MANCUSO; DEMETRI *
 DERMATOLOGY; DEMETRI *
 DERMATOLOGY AND COSMETIC *
 CENTER; DR. ELIZABETH DEMETRI; *
 DR. MEDHI MOSADEGH; DR. JORGE CRUZ; *
 DR. THOMAS ORGERON; DR. JOEL *
 PERDOMO; RAINEY & FINKLEA *
 DERMATOLOGY AT CASTLE HILLS; *
 DR. LINDSEY FINKLEA; BRANSON *
 DERMATOLOGY; DR. CHRISTIE RAINEY; *
 SOUTHERN ILLINOIS DERMATOLOGY; *
 DR. TED G. VAN ACKER; ADVANCED *
 DERMATOLOGY & LASER; DR. NITA *
 PATEL; GAUGHF DERMATOLOGY; *
 DR. CLAUDIA GAUGHF; ASPEN *
 DERMATOLOGY; DR. MICHAEL EYRE; *
 BAYSIDE DERMATOLOGY; DR. DONALD *
 BROWN; MCGUINESS DERMATOLOGY; *
 DR. MICHAEL MCGUINESS; DR. GRACE *
 BROWN; DR. SHAILY KESASNI; DR. LEISA *
 HODGES; DR. ELBA RUBIANES; *
 DR. STEVEN EILERS; DR. FELICIA EKPO; *
 ATLANTA DERMATOLOGY; DR. JEFFREY *
 COOPER; DR. RAVEN ELOISEBO-WALKER; *
 DR. JOHNATHAN CHAPPELL; AGHA *
 ADVANCED DERMATOLOGY; DR. AMR *
 AGHA: COLE DERMATOLOGY & *
 AESTHETICS, CENTER PC; DR. KENDRA A.*
 COLE; THE DERMATOLOGY GROUP; *
 DR. DINA V. HUNTER; DR. LEE T. JORDAN; *
 DR. SCOTT A. MAISCH; SKIN CANCER *
 CENTER; DR. RICHARD J. DEANGELIS; *
 DERMATOLOGY ASSOCIATES OF *
 COASTAL CAROLINA: DR. JAMES M. *
 POLO; DR. SEAN J. MURPHY; DR. SCOTT *

MCCLELLAN; DR. CYNTHIA A. POLO; *
 PIEDMONT PLASTIC SURGERY AND *
 DERMATOLOGY; DR. DANIEL T. *
 NESS; DR. GREGORY A. MANTOOTH; *
 DR. GREGORY M. SWANK; DR. MIGUEL A. *
 YANEZ; DR. BENSON TIMMONS; DR. ERIC *
 T. EMERSON; DR. POARAG BUTALA; DR. *
 STEVEN A. SICILIANO; DR. ROSIANE A. *
 ROEDER; DR. BENJAMIN R. ESKENAZI; *
 DR. DARRELL W. FREEMAN; DR. DORI L. *
 HUNT; DR. CHARLES S. JOHNSON; *
 DR. PATRICK MCELGUNN; DR. TONYA S. *
 MCLEOD; DR. WILLIAM L. FANGMAN; *
 DR. LAURA B. ROSENZWEIG; DR. JAIME J. *
 FANOURY; DR. LAURA KLINE; DR. JOSHUA *
 G. PORTER; DR. CHRISTOPHER A. *
 SNYDER; DR. JERRY L. PRUITT; *
 DR. DONALD D. FRASER; DR. BETHANY M. *
 BERGAMO; DR. GEORGE D. MAGEL; *
 DR. KRISTEN B. HIGGINS; DR. NANCY J. *
 ASTLE; DR. EUPHEMIA W. MU; *
 DR. ROBERT J. HAWK; DR. LARRY A. *
 NAPOLITANO; KMC DERMATOLOGY; *
 DR. MICHAEL KUCENIC; DR. JOSEPH *
 GADZIA; DR. MEENA SINGH; DR. KYLE *
 ANDERSON; DR. JAMES ALLEN; *
 DR. MAJDY ALBAHHAR; DR. LISA *
 WAXMAN; DR. LEE BITTENBENDER; *
 DR. DAVID MARTELL; DERMASSOCIATES, *
 LTD; DR. GARY VICIK; RANDALL *
 DERMATOLOGY AND MEDSPA; DR. JOHN *
 K. RANDALL; HOLLAND DERMATOLOGY; *
 DR. BARBARA DROZDOWSKI; SUMMIT *
 DERMATOLOGY; DR. THOMAS MYERS; *
 READING DERMATOLOGY; DR. JASON *
 HENDRIX; DR. DEAN BURGET; DR. STEVEN *
 SCHLEICHER; LASERDERM *
 DERMATOLOGY AND COSMETIC LASER *
 SURGERY; DR. DONNA A. SENURE; *
 DR. AUDRA M. MALERBA; DR. ELENA *
 MAYDAN; DERMATOLOGY & SKIN *
 CANCER SURGERY CENTER; *
 DR. MATTHEW BARROWS; DR. HEATHER *

FROEHLICH; DR. CLARA HENRY;	
DR. CHRIS HIXON; DR. MATTHIAS	*
SOLOMON; AESTHETIX DERMATOLOGY;	*
DR. IGOR CHAPLIK; POLLEY CLINIC OF	*
DERMATOLOGY AND DERMATOLOGIC	*
SURGERY, P.A.; DR. DENNIS POLLEY;	*
TOTAL SKIN AND *BEAUTY	*
DERMATOLOGY CENTER; DR. GARY D.	*
MONHEIT; DR. JAMES M. KRELL;	*
DR. MELANIE L. APELL; DR. A. MICHELLE	*
HILL; DR. RAJINI MURTHY; BOOTH	*
DERMATOLOGY AND COSMETIC CARE	*
CENTER; DR. SALLY A. BOOTH;	*
MIDDLESEX DERMATOLOGY;	*
DR. ERIC J. THOMAS; LEHIGH VALLEY	*
DERMATOLOGY ASSOCIATES. LTD;	*
DR. DAVID B. VASILY; DYERSBURG	*
SKIN AND ALLERGY CLINIC PROVIDERS;	*
DR. KENTON BUSCH; ADVANCED SKIN	*
AND MOHS SURGERY; CLARENCE W.	*
BROWN; DERMATOLOGY & SKIN	*
CANCER CENTER OF SOUTH CAROLINA;	*
DR. JOSEPH M. MASESSA; OAKLAND	*
HILLS DERMATOLOGY P.C.;	*
DR. CHRISTOFER BUATTI; TAREEN	*
DERMATOLOGY; DR. MOHIBA TAREEN;	*
DR. LORRAINE GRIFFIN; DR. RYAN	*
HOLZWARTH; FOREFRONT	*
DERMATOLOGY, D/B/A DERMATOLOGY	*
CENTERS OF NORTHWEST INDIANA, PC;	*
DR. ASHVIN GARLATI; DR. MITCHELL	*
BRESSACK; TRU-SKIN DERMATOLOGY	*
DR. S. ROBERT HARIA; DR. CARLO LAVINO*	
DR. TANYA KHAN; DR. LIQIAO MA;	*
MUSICK DERMATOLOGY, LLC;	*
DR. STEVEN MUSICK;	*
	*
Defendants.	*

**ORIGINAL VERIFIED COMPLAINT UNDER THE
FEDERAL FALSE CLAIMS ACT**

Plaintiff-Relator, Daniel W. Creger, (“Relator” or “Cregger”), through his attorneys, on behalf of the United States of America, (the “Government” or the “Federal Government”), for his Original Verified Complaint under the Federal False Claims Act ¹, the *Stark Law* ² and the Anti-Kickback Statute³ , and also on behalf of the several captioned States, (“the States”), under their respective False Claims Acts; with the allegations of such Verified Complaint not relying upon publically disclosed documents or information; but should they be deemed in any respect to do so, Relator is the original source of such information to the Government and to the States; against Defendants, Pinnacle Dermatology, LLC, (“Pinnacle”); SkinCure Oncology, LLC, (“SkinCure”); Chad A. Eckes, (“Eckes”); Chicago Pacific Founders; Mary Tolan, (“Tolan”); Dr. Jose Rios, (“Rios”); Dr. Paula K. Lapinski, (“Lapinski”); Kerwin J. Brandt, (“Brandt”); Dr. Daniel J. Ladd, (“Ladd”); Krista Hatcher, (“Hatcher”); Vance Varnier, (“Varnier”); Steven B. Bonner, (“Bonner”); Steven L. Scott, (“Scott”); L. Peter Smith, (“Smith”); CapX Partners, (“CapX”); Jeffrey Preffer, (“Preffer”); Fountain Partners, (“Fountain”); Tom Carter, (“Carter”); John Van Hooser, (“Van Hooser”); and the several other Dermatology Practices and Dermatologists otherwise named in the caption of this Verified Complaint whose names, addresses and contact information are attached to this Verified Complaint as Exhibit A; which Exhibit in its entirety is incorporated by reference into the body of the language

1 31 U.S.C. § 3729 *et seq.*

2 42 U.S.C. § 1395nn

3 42 U.S.C. § 1320a-7b(b).

of said Complaint, (sometimes collectively “defendants,” or “co-conspirator defendants” or in the case of the Dermatology Practice(s) or Dermatologist(s), Defendants, “Co-conspirator Dermatologist(s)”),⁴ alleges under the Qui Tam provisions of the False Claims Act and similar provisions of comparable State False Claims Acts, in camera and under seal, based upon personal knowledge and relevant, and material documents as follows:

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I. Introduction

1. This case is about defendants’ payment or receipt of bribes or kickbacks or their unlawful referrals of designated health services, (“DHS”), in exchange for such bribes and kickbacks and their conspiracy. The fraud and conspiracy of every defendant began in 2016 with the three individuals who co-founded defendant, SkinCure Oncology, (“SkinCure”): Dr. Daniel J. Ladd, Steven L. Scott and L. Peter Smith. They master-minded a fraudulent marketing scheme by paying co-conspirator dermatologists across the country, kickbacks and bribes, to obtain referrals and gain access to their patients to whom they then unlawfully provided DHS5 in the form of superficial radiation therapy treatment for non-melanoma skin cancers. SkinCure called their scam the “SRT Turnkey Implementation Program.” It violated the *Stark* Law and the Anti-Kickback Statute.⁶ But it is about much more: a nationwide fraud and conspiracy to present false claims to Medicare and other federal and State healthcare programs for payment and for SkinCure to avoid paying at least \$15,000,000 in sales and use taxes to the State of Illinois.

5 42 U.S.C. § 1395nn(h)(6).

6 42 U.S.C. § 1395nn; 42 U.S.C. § 1320a-7b(b).

2. SkinCure's "SRT Turnkey Implementation Program" paid co-conspirator, dermatologists kickbacks and bribes, by furnishing them, at no cost, the following valuable items and services (1) a \$495,000 SRT-100-Vision machine, (sometimes, "SRT machine") (Owned by SkinCure); (2) a radiation therapy technician, (employed and paid by SkinCure); (3) billing and collection services, (performed by SkinCure paid employees); (4) State radiation registrations and filings, (paid for by SkinCure and performed by its employees); (5) services of a Medical Physicist, (employed and paid by SkinCure); (6) services of an account manager, (employed and paid by SkinCure); (7) design and construction of a lead lined room at the dermatologist's office, at SkinCure's expense, to safely accommodate the SRT machine; among other illegal remuneration.

3. But the big money bribe and kickback SkinCure paid co-conspirator dermatologists was 40% of every Medicare reimbursement for cancer treatment services performed in the dermatologist's office by SkinCure using the SkinCure owned SRT radiation therapy machine, operated by the SkinCure radiation therapy technician, on the dermatologist's patients who had been unlawfully referred to SkinCure and were Federal or State healthcare program beneficiaries. Receipt of these bribes and kickbacks gave every dermatologist who contracted with SkinCure a financial interest in SkinCure, making their referrals of Medicare beneficiaries, *Stark* Law violations.⁷ Kickbacks were "Illegal Remunerations and AKS violations."⁸ Defendants' violations of both laws, were False Claims Act violations.⁹

7 42 U.S.C. § 1395nn(a)(1).

8 42 U.S.C. § 1320(b)

9 *United States ex rel. Augustine v. Century Health Services*, 289 F. 3d 409 (6th Cir. 2002).

4. The Government and the States were, at all material times, completely unaware that SkinCure had paid kickbacks and furtively placed a \$495,000, SkinCure owned, SRT superficial radiation therapy machine and a SkinCure radiation therapy technician into their co-conspirator, dermatologist's office at no charge, in exchange for the dermatologist's unlawful referrals so SkinCure could then secretly provide DHS in the form of superficial radiation therapy on the dermatologists' patients. The Government and the States were also completely unaware that SkinCure was paying the dermatologists other kickbacks—especially 40% of every reimbursement received from all Federal and State healthcare programs¹⁰ for such services.

5. SkinCure completed the fraud by tightly controlling the Medicare billing process for radiation treatment SkinCure provided to Medicare beneficiaries using the SkinCure SRT machine in the name of the dermatology practice, fraudulently using the dermatology practice's Medicare/Medicaid Provider/Supplier Billing Number. This was done because, at no material time, was SkinCure an approved Medicare/Medicaid Provider/Supplier. At no material time, did SkinCure possess a valid Medicare/Medicaid, Provider/Supplier, Billing Number. At no material time was SkinCure qualified or approved to provide any DHS to Medicare beneficiaries. Therefore, SkinCure's provision of such DHS in the form of radiation therapy treatment for its co-conspirator dermatologist's Medicare patients was fraudulent, violated *Stark*, AKS and the False Claims Act.

6. From the co-conspirator dermatologist's point of view, it was a beautiful scheme: at no expense, they captured 40% of the Medicare reimbursement, in exchange for unlawfully referring

¹⁰ "Medicare" will be Relator's preferred, but not exclusive term, to identify Federal and State Healthcare programs.

their Medicare patients to SkinCure for it to provide them with DHS, superficial radiation therapy services. Previously they had either excised such cancerous lesions themselves or referred such patients to a Mohs Surgeon for microscopic excision, capturing 0% of the Government reimbursement for the Mohs procedure. According to the medical literature, and the American Academy of Dermatology, Mohs Surgery remains the Gold Standard for treating the vast majority of more difficult, non-melanoma skin cancer presentations. Typical Medicare reimbursement for a Mohs Surgery is about \$1500 per lesion. Medicare reimbursement for SRT treatment of non-melanoma skin cancer is \$7000-\$10,000, per lesion or five to seven times greater. Medicare's significantly greater reimbursement regime for SRT treatment of these skin cancers is the gasoline fueling SkinCure's fraud and conspiracy, its presentation of false invoices to Federal and State healthcare programs for payment and the over utilization of SRT treatment.

7. The law is clear. Any violation of *Stark* or the Anti-Kickback Statute is a violation of the False Claims Act.¹¹ Defendants are guilty of violations of each. Neither SkinCure, nor any other defendant, ever sought an advisory opinion from OIG about whether the SkinCure, SRT Turnkey Implementation Program complied with *Stark* or AKS.

8. SkinCure and its co-conspirator defendants are each guilty of knowingly presenting

¹¹ 42 U.S.C. § 1320a-7b(g): "Kickbacks. In addition to the penalties provided in this section or Section 1128A[1320a-7b], a claim that items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of sub-chapter III of chapter 37 of title 31 U.S.C. § 3721 *et seq.*" That provision added by the Patient Protection and Affordable Care Act of 2010. 31 U.S.C. § 3729 (a)(1)(A),(B) & (C); *United States ex rel. Pogue v. American Healthcorp., Inc.*, 914 F. Supp. 1507 (M. D. Tenn. 1996).

false invoices to Medicare for payment or conspiring to do so.¹² SkinCure and its co-conspirator defendants are each guilty of knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or conspiring to do so.¹³ SkinCure and its co-conspirators are guilty of collusion to enable SkinCure to avoid at least \$15,000,000 in sales and use taxes which it owed the State of Illinois.

9. Furthermore, SkinCure and each co-conspirator dermatologist are guilty of falsely certifying, expressly and impliedly, that they are in compliance with Medicare laws and other Federal and State healthcare program regulations, and program instructions, including their false implied certifications that they were in compliance with *Stark* and the Anti-Kickback Statute.

10. Each defendant, with full knowledge that they were not entitled to receive any reimbursements from Federal or State healthcare programs, have willfully refused to reimburse the United States and the States for such monies they have unlawfully received.¹⁴

11. Relator, as will be shown, is also entitled to a separate judgment against defendant, Pinnacle for its retaliatory discharge of him because he engaged in covered, protected conduct.¹⁵

12. The fraudulent conduct and conspiracy of the defendants does not qualify for any exception or “Safe Harbor” under *Stark* or the Anti-Kickback Statute. Defendants are guilty of

12 31 U.S.C. § 3729 (a)(1)(A)&(C).

13 31 U.S.C. §3729 (A)(1)(B)&(C).

14 31 U.S.C. §3729 (a)(1)(C) & (G).

15 31 U.S.C. §3730 (h).

violating both and under the False Claims Act are liable for treble the actual damages caused the United States and the States, together with, penalties, statutory attorney's fees, interest, prejudgment interest and costs, all of which this suit demands.

II. The Parties

The Plaintiff, Daniel W. Creger

13. The Plaintiff, Daniel W. Creger, is over twenty-one years of age and resides at 5105 Camelliaview Way, Smyrna, Tennessee 37167. He received a Bachelor of Science Degree, with Cum Laude Honors, from the College of Applied Sciences at Western Illinois University. He has been employed in healthcare for over 25 years in a variety of executive capacities. Initially after college, his work focused on pharmaceutical sales, marketing and training, while he worked for Forest Pharmaceuticals, Inc., Centocor, Inc., Kos Pharmaceuticals, Elli Lilly & Co., and Biogen Idec, Inc. After about ten years, his career path moved into healthcare consulting and management in the field of Dermatology. Beginning in July 2011, he became Director of Strategic Initiatives at Dermatology Associates of Wisconsin, where he was employed for two-and-a-half years. During his tenure, he conducted the business evaluations necessary to acquire ten dermatology practices, with 26 dermatologists, negotiating each merger/acquisition and all physician contracts. He also authored a "Mission and Vision Statement" for the company. During this time, he also conducted his own personal research and investigation into the Stark Law, the Anti-Kickback Statute and the False Claims Act.

14. In January of 2014, Creger formed and was president and CEO of Dermatology Practice Consultants, Inc. For the next two-and-a-half years, he was an independent consultant to Dermatology Practices and engaged in recruiting physicians, advising a regional dermatology

platform in what turned out to be its successful acquisition by a private equity group. He kept up with the Stark Law, the Anti-Kickback Statute and the False Claims Act. He directed capital purchases of durable equipment, obtaining necessary certifications and certificates of compliance, while preparing pro forma economic projections, estimated project costs and recommended marketing plans and initiatives to ensure a successful endeavor. His consulting recommendations resulted in enhanced revenue streams for dermatology practices. He developed Mission and Vision Statements for dermatology practices and platforms. He designed marketing strategies, press releases and brochures to promote the business activities of the dermatology practices and platforms with whom he consulted.

15. In late March 2017, Creger was approached by a headhunter, informed of the opportunity and interviewed for the open CEO position at defendant, Pinnacle. To schedule and arrange for the interview, he was not contacted by anyone at Pinnacle. He was contacted by Krista Hatcher, partner at Chicago Pacific Founders, which had just made its first loan to Pinnacle in March 2017. He flew to Chicago from Nashville on the afternoon of April 18, 2017, had dinner with defendants, Rios and Lapinski, that evening. But his formal interview did not occur at the Pinnacle offices. He never even saw the Pinnacle offices. The formal interview occurred the next day, April 19, at the Chicago Pacific offices at 980 North Michigan Avenue, Suite 1998, Chicago Illinois 60611. During the formal interview, Creger was not interviewed by a single Pinnacle employee, nor was one ever present. He was interviewed by defendant, Mary Tolan, the founder of Chicago Pacific Founders, and its partners and defendants, Krista Hatcher and Greg Kazan. The interview lasted from about 8:00 A.M. until about 2:00 P.M. Creger was required to sign a confidentiality agreement by Chicago Pacific partners as a condition for the interview. Creger's reimbursements for plane fare,

hotel bill, rental car and other travel expenses were all paid, not by Pinnacle—but by Chicago Pacific Founders. Creger was not hired as CEO of Pinnacle.

16. *In May 2017, Creger became the CEO of Tennessee Dermatology Partners, Inc., located in Nashville. Under his leadership it became the largest dermatology group in Tennessee with 35 providers in 18 locations throughout the state. Relator engaged in vendor negotiations and did pro forma analysis on proposed capital purchases for strategic locations and impact studies for new technologies. He kept up with the Stark Law, AKS and the False Claims Act while so employed. In October 2017, Relator and Dr. John Q. Binhlam, a dermatologist at Brentwood Dermatology, an affiliate of Tennessee Dermatology, were approached by defendant, Brandt, of SkinCure and negotiations began for Brentwood to sign up for the SRT Turnkey Implementation Program and for SkinCure to provide, at no charge, a Sensus SRT-100-Vision machine,¹⁶ (purchase price \$495,000), a radiation therapy technician and billing services among other things. Brandt sent a proposed Program Services Agreement with 14 pages of extensive terms and conditions, together with a proposed Business Associates Agreement and Medicare Billing Allowables for 2017. Relator and Dr. Binhlam each concluded that the SkinCure proposal made by Brandt, and confirmed by the contract documents provided, did not comply with the Stark Law, Anti-Kickback Statute or the False Claims Act. They rejected the proposal Brentwood Dermatology never contracted with SkinCure.*

17. In June 2018, Creger successfully negotiated the purchase from manufacturer Sensus of a small SRT 100 Radiation Therapy Machine for Tennessee Dermatology affiliate, Dr. Keith Loven, a dermatologist owning three Dermatology Practices in Goodlettsville, Henderson and

¹⁶ The complete technical name for this machine is the Sensus SRT-100-Vision Machine.

Hermitage, Tennessee. The smaller SRT machine cost about \$160,000. Creger's employment with Tennessee Dermatology has just concluded. For a time, with full disclosures and permission, Creger was employed simultaneously by Defendant, Pinnacle, and Tennessee Dermatology

18. The period of such dual employment began in September 2019, when Creger was hired by Pinnacle as its Chief Growth Officer. Terms of that employment, were set forth in a written employment agreement,¹⁷ negotiated with defendant, Eckes. Creger's chief responsibilities as Chief Growth Officer were to expand the company by recruiting new Dermatologists, acquiring new Dermatology Practices. But he also negotiated savings on cosmetic purchases that saved the company about \$300,000 annually. He also negotiated the acquisition of a new Dermatology practice, projected to add at least \$400,000 in annual earnings. He also performed pro forma analysis and conducted impact studies of new technology lines of service for Pinnacle such as in-house pharmacy dispensing.

19. Creger was a member of Pinnacle's Executive Leadership Team, (ELT), which was comprised of its executive management.¹⁸ The ELT met every week to discuss Pinnacle's business operations, including expanding its system of Dermatology Practices, financial results, strategic initiatives and planning and setting operations, financial and marketing goals for the company. The members of the ELT team were the hands-on executives responsible for the business and financial

¹⁷ See Exhibit B, Creger's Employment Agreement with Pinnacle.

¹⁸ The executive management members of the ELT were CEO, Chad Eckes, COO, Matt Renn, Vice President Operations, Barbara Dominic, Board of Directors President, Mary Tolen, Founders and Major Stock Owners of Pinnacle, Dr. Jose Rios, and Paula Lapinski, Mr. L. Peter Smith, Consultant and Advisor

success of the company.

20. During his August 2019, interview with Eckes, Creger learned that Pinnacle had signed up for the SkinCure SRT Turnkey Implementation Program, which included a personal services term allowing SkinCure to bill Medicare and other Federal and State healthcare programs under Pinnacle's Tax ID Number and its Medicare, Provider/Supplier Billing number. He told Eckes, during the interview, that he did not think the scheme was proper. Throughout his six month employment with Pinnacle, Creger had several conversations with Eckes about the SkinCure scheme. *During each such conversation, Creger told Eckes that he did not think the scheme was proper. The conversations, which will be discussed in greater detail later, were protected, covered conduct under 31 U.S. C. § 3730(h). On March 13, 2020, shortly after Creger had told Eckes, again, that Pinnacle's contract with SkinCure was not proper, Eckes telephoned Creger and terminated his employment with Pinnacle.*

Defendant, Pinnacle Dermatology, LLC.

21. Pinnacle Dermatology, LLC, a privately owned company, was formed in 2004 by Defendants, Dr. Jose Rios, and Dr. Paula Lapinski, with its current principal corporate offices located at 820 Springer Drive, Lombard, Illinois 60148. Pinnacle touts itself as a "Chicago Pacific Founders portfolio company . . . [with] . . . more than 100 providers and 51 convenient locations in Greater Chicagoland, Northwest Indiana, the Indianapolis area, Tennessee, Minnesota, Michigan and poised for further expansion." Its business is the practice of Dermatology. It currently employs between 500 and 1000 people across its five state service area.

22. In March 2017, Pinnacle aligned with defendant, Chicago Pacific Founders, receiving an infusion of investment capital from them, which it then deployed to acquire Dermatology

Practices across its service area. Pinnacle apparently chose Chicago Pacific to be its financier because, “[it was] one of the only healthcare based investment funds in dermatology, to create an alternative model to national dermatology practices.”¹⁹ Creger is the original source of this information. Since March 2017, Pinnacle has purchased no less than 16 Dermatology Practices adding scores of new providers and treatment locations, all fueled by Chicago Pacific investment capital.

23. To protect its investment, Chicago Pacific placed its founding members and managing partners, Mary Tolan and Vance Vanier, on the Pinnacle Board of Directors, with Tolan as board president. Chicago Pacific partner, Krista Hatcher, and Pinnacle advisor, Steven B. Bonner, also became Pinnacle voting board members. From about March 2017, Tolan, Vanier, Hatcher and Bonner were four of the seven voting members on the Pinnacle Board of Directors. Since then, they have maintained complete control of the Pinnacle Board.

Defendant, SkinCure Oncology, LLC

24. Defendant, SkinCure Oncology, LLC, was founded and incorporated in the State of Delaware on October 10, 2016, with its principal place of business located at 745 McClintock Drive, Burr Ridge, Illinois 60527. Its Chief Executive Officer is Kerwin J. Brandt who has been an aggressive marketer for the company all over the country. The company was founded by Dermatologist, Dr. Daniel J. Ladd, who is also the company’s Chief Medical Officer and one of its major equity holders, Steven L. Scott, Chief Operating Officer of SkinCure and L. Peter Smith, an experienced healthcare entrepreneur and SkinCure equity owner.

25. From inception, SkinCure has been fraudulently: (1) paying bribes and kickbacks to

¹⁹ See Exhibit C, Paylocity Internet Pinnacle Press Release.

dermatologists in exchange for their unlawful referrals of Medicare patients for superficial radiation therapy services, DHS; (2) billing Medicare under the dermatology practice's Medicare Provider/Supplier Number because SkinCure is not an approved Medicare Provider/Supplier for any item or service. At no material time has SkinCure ever lawfully possessed an approved Medicare Provider/Supplier Number. Also, SkinCure is not a lawful agent of the Dermatology Practice qualified to present for payment bills to Medicare, because, among other reasons, its fees for billing take into account the volume and value of the bills submitted to Federal and State healthcare programs. SkinCure's bribe and kickback scheme does not qualify for exceptions under the *Stark* Law or Safe Harbors under the Anti-Kickback Statute. SkinCure has also conspired with its co-conspirator dermatologists to avoid paying at least \$15,000,000 in sales and use taxes to the State of Illinois.

26. Since 2016, SkinCure has placed 200 or more SRT Machines in dermatology offices principally in the east, south and mid-west but also in Los Angeles, Chicago, Houston, Atlanta, and New York. SkinCure brags that, "Our core competency centers on striving to be the Dermatologist's 'aspirin' in all aspects of SRT solutions for their patients." SkinCure's current sales pitch to market its unlawful program for SRT treatment for non-melanoma skin cancers is that "SRT is the new 'Gold Standard' for [treating all such cancers]." In other words, SkinCure's business plan is to replace the "Gold Standard" treatment for most non-melanoma skin cancers—Mohs surgery—with their fraudulent, "SRT Turnkey Implementation Program." They have enlisted the aid of co-conspirator dermatologists by paying them kickbacks and bribes to substitute SkinCure's SRT treatment for simple excision or Mohs surgery to treat non-melanoma skin cancers. The unlawful SkinCure program relies on overutilization of superficial radiation therapy and the submission of

false invoices for payment to Medicare to achieve their “Pot of Gold” aspirations. By the end of 2020, it will have collected reimbursements for itself and its dermatologist co-conspirators, unlawful reimbursements, from Medicare, Medicaid, other Federal and State healthcare programs that exceed \$200,000,000. Relator is the original source of any publically disclosed information related to SkinCure herein

Defendant, Chad A. Eckes

27. Defendant, Chad Eckes, has at all material times conducted business activities within the jurisdiction of this Court. Since 2017, Eckes, has been the Chief Executive Officer of Pinnacle with offices at its headquarters in Lombard, Illinois. He negotiated Pinnacle’s contract with defendant, SkinCure—the SRT Turnkey Implementation Program--which resulted in the knowing, unlawful referrals of Federal healthcare program patients to SkinCure in return for Pinnacle’s receipt of unlawful kickbacks paid by SkinCure, all in violation of the *Stark* Law and the Anti-Kickback Statute. Eckes knew, should have known, or recklessly disregarded the fact that the SRT Turnkey Implementation Program violated *Stark* and the Anti-Kickback Statute. Early in 2020, during an Executive Leadership Team meeting, Relator heard Eckes tell the group that “I’ve got to talk to Kerwin [Brandt] about us [Pinnacle] getting paid, [Pinnacle’s 40% split of the Medicare reimbursements.]” This was an admission by the Pinnacle CEO that Pinnacle was receiving bribes and kickbacks from SkinCure in exchange for its Medicare patient referrals. Relator believes that Eckes may have recently moved his residence to the Nashville area, within the jurisdiction of this Court.

Defendant, Chicago Pacific Founders

28. Chicago Pacific Founders was formed in April 2014 by defendant, Mary Tobin,

among others, as a private equity investment enterprise, with its principal place of business located at 980 North Michigan Avenue, Suite 1998, Chicago, Illinois 60611, but it was, and has been, at all material times doing business in the State of Tennessee and within the jurisdiction of this Court. The company touts itself as a strategic healthcare services company. The company will invest up to \$75,000,000 of equity capital per opportunity in buyout and growth transactions for cash flow positive businesses.

29. In March 2017, Chicago Pacific made a substantial investment in Pinnacle Dermatology, apparently taking a substantial equity stake in Pinnacle. To protect that stake, Chicago Pacific placed four partners on the seven voting member Board of Directors of Pinnacle, thereby gaining complete control of the business activities of Pinnacle. With Chicago Pacific's financial backing, Pinnacle began aggressively acquiring dermatology practices in its five state area of operation. Chicago Pacific Founders in August 2019, through the actions of its partners Mary Tolan, Krista Hatcher, Vance Varnier and Steven Bonner, each of whom voted as Pinnacle board members in favor of Pinnacle entering into the SRT Turnkey Implementation Program with SkinCure. With their votes in favor of SkinCure's fraudulent Program, they each, and Chicago Pacific, became co-conspirators to defraud Medicare.

Defendant, Mary Tolan

30. Defendant, Mary Tolan, is a resident of a state other than the State of Tennessee but at all material times she has conducted business activities within the jurisdiction of this Court. Tolan was an original founder of the private equity firm, Chicago Pacific Founders with its principal place of business in Chicago. However, she has had a checkered business history. She was forced to resign as CEO of Accretive Health in the fall of 2013 after it was de-listed from the New York Stock

Exchange and investigated by the Minnesota Attorney General for financial improprieties and questionable debt collection practices. The company was forced to restate its financial reports for 2011, 2012 and 2013 because it did not properly book revenues and expenses during those years. Shortly thereafter, in April 2014, she founded Chicago Pacific. Her bio at Chicago Pacific touts that she is “bringing private equity into healthcare provisions . . . creating transformative changes to a field in eager need of them . . . Mary’s experience had proved the ideal preparation.”

31. Under Tolan’s leadership, in March 2017, Chicago Pacific first loaned money to Pinnacle to fuel its rapid expansion through purchases of private Dermatology Practices in Minnesota, Illinois, Indiana, Michigan and Tennessee. A second loan was approved and facilitated by Tolan in May 2018. Since March of 2017, Tolan has been Chairman of the Board of Directors of Pinnacle and an influential voting member.

32. Tolan knew about, and approved of, the contract between Pinnacle and SkinCure, which resulted in the knowing, unlawful referrals of Federal healthcare program patients to SkinCure in return for Pinnacle’s receipt of unlawful kickbacks paid by SkinCure, all in violation of the *Stark* Law and the Anti-Kickback Statute. Defendant Chad Eckes reported during the Executive Leadership Team meeting on October 22, 2019, that during the Pinnacle Board meeting on October 16, 2019, “Board Members are pleased with trajectory, don’t want to give up what the budget was. Keep driving forward on all these fronts. . . Volume, charging enough, collecting enough and billable services i.e. Cool Sculpting and SRT. Overall pleased with results. . . .” Eckes told Creger that Tolan was present and chaired the October 16 Board meeting. Tolan, Hatcher, Varnier and Bonner were driving forces in approving and perpetuating Pinnacle’s unlawful contract with SkinCure. They each knew about, should have known about or recklessly disregarded, the fraud perpetrated against

Medicare by SkinCure's SRT Turnkey Implementation Program.

Defendant, Krista Hatcher

33. Defendant, Krista Hatcher, is a resident of a state other than the State of Tennessee but she, at all material times, has done business in Tennessee and within the jurisdiction of this Court. According to her Pinnacle bio, as a voting member of its Board of Directors, Hatcher is a partner at Chicago Pacific Founders and is responsible for sourcing and leading investments in healthcare and senior living. Throughout her career she has worked successfully with founder-led growth companies to develop and execute strategies for sustainable, profitable growth and value creation. Working with executives at these companies, Hatcher has led strategic initiatives involving business development, add-on acquisitions, enhancement of operational efficiencies, and the recruitment, development and integration of the key management talent and teams needed to help these businesses successfully scale. She has also been very effective at leading and executing successful, value optimizing exit strategies for the high growth companies with which she has worked.

34. Hatcher knew about, and approved of, Pinnacle's unlawful contract with SkinCure, which made Pinnacle a co-conspirator through the SRT Turnkey Implementation Program, to defraud Medicare.

Defendant, Dr. Vance Varnier

35. Defendant, Dr. Vance Varnier, is a resident of a state other than the State of Tennessee but he, at all material times, has done business in Tennessee and within the jurisdiction of this Court. According to his Pinnacle bio, as a voting member of its Board of Directors, Hatcher

is a partner at Chicago Pacific Founders. Dr. Varnier is a medical doctor but has been an executive and investor in healthcare companies for the past 15 years or more. As a member of Pinnacle's Board, Varnier knew about, approved of, and voted to implement Pinnacle's unlawful contract with SkinCure. Such contract made Pinnacle a co-conspirator through the SRT Turnkey Implementation Program, to defraud Medicare.

Defendant, Dr. Jose Rios

36. Defendant, Dr. Jose Rios, is a medical doctor, President and co-founder of Pinnacle in 2004. His principal place of business is in the Chicago area, but at all material times he has done business in the State of Tennessee and within the jurisdiction of this Court. Relator does believe that Dr. Rios may have moved his residency recently to the Nashville area.

37. Dr. Rios is a voting member of the Board of Directors and Leadership Team of defendant, Pinnacle Dermatology. He knew about, approved of, and voted to implement, Pinnacle's unlawful contract with SkinCure. Such contract made Pinnacle a co-conspirator through the SRT Turnkey Implementation Program, to defraud Medicare.

Defendant, Dr. Paula Lapinski

38. Defendant, Dr. Paula Lapinski, is a medical doctor, co-Chief Medical Officer and co-founder of Pinnacle in 2004. She is a member of the Leadership Team of defendant, Pinnacle Dermatology. Her medical specialty is dermatology and she is a fellowship-trained Mohs micrographic surgery specialist. She has 10 office locations in the Chicago area where she practices, including Joliet, Frankfurt, Bourbonnais, Ottawa, Valpariso, La Porte, Oak Lawn, Hoffman Estates, Greenfield and Decatur, Illinois, but at all material times she has done business in the State of Tennessee and within the jurisdiction of this Court. Relator does believe that Dr. Lapinski may have

moved her residency recently to the Nashville area. She is married to defendant, Dr. Rios.

39. Dr. Lapinski is a voting member of the Board of Directors of Pinnacle. She is also a Pinnacle dermatology administrator at its dermatology therapy clinic located at 1124 Essington Road, Joliet, Illinois 60435-8423. In her capacity as administrator, on September 13, 2019, she registered the Sensus, Model: SRT-100-Vision, superficial radiation therapy machine, bearing Equipment ID No.: 7500, Class: Thr50-120kvp, Serial No.: 1903-2126, with said machine being owned by defendant, SkinCure, but provided to defendant, Pinnacle, at no charge, and acquired by Pinnacle's Joliet Therapy Clinic on September 5, 2019. Dr. Lapinski knew about, approved of, and voted to implement Pinnacle's unlawful contract with SkinCure. Such contract made Pinnacle a co-conspirator through the SRT Turnkey Implementation Program, to defraud Medicare.

Defendant, Kerwin J. Brandt

40. Defendant, Kerwin J. Brandt, is a resident of a state other than the State of Tennessee but he, at all material times, has done business in Tennessee and within the jurisdiction of this Court. Brandt is the Chief Executive Officer of defendant, SkinCure. He negotiated Skincure's contract with defendant, Pinnacle, which resulted in the knowing, unlawful referrals of Federal healthcare program patients to SkinCure in return for Pinnacle's receipt of bribes and kickbacks paid by SkinCure, all in violation of the *Stark* Law and the Anti-Kickback Statute.

41. While Creger was CEO of Tennessee Dermatology, Brandt met with Creger and Dr. Binhlam on November 8, 2017, to propose and discuss the details of the SRT Turnkey Implementation Program. After reviewing the proposed contract and considering everything Brandt had to say during their meeting, Creger and Dr. Binhlam both concluded that SkinCure's contract was unlawful and would result in the knowing, unlawful referrals of Federal healthcare program

patients to SkinCure in return for receipt of unlawful bribes and kickbacks paid to Dr. Binhlam's practice by SkinCure, all in violation of the *Stark* Law and the Anti-Kickback Statute. Dr. Binhlam rejected Brandt's SkinCure contract proposal. To be clear, Dr. Binhlam never signed SkinCure's proposed contract. Undaunted, Brandt successfully negotiated SRT Turnkey Implementation Program contracts with The Skin Wellness Center in Knoxville in early 2019 and with Pinnacle's Murfreesboro Dermatology, in August 2019. Brandt knew, should have known or recklessly disregarded the fact that the SkinCure SRT Turnkey Implementation Program violated *Stark*, the Anti-Kickback Statute and the False Claims Act.

Defendant, Dr. Daniel J. Ladd

42. Defendant, Dr. Daniel J. Ladd, is a resident of a state other than the State of Tennessee, but at all material times has conducted business in the State of Tennessee and within the jurisdiction of this Court. Dr. Ladd is a Dermatologist/Mohs Surgeon with his principal place of business located at: 3500 Jefferson Street, Suite 200, Austin, Texas 78731, where he founded Tru-Skin Dermatology. Tru-Skin also has dermatology offices, where Dr. Ladd practices, in Bastrop, LaGrange and Kerrville, Texas. Dr. Ladd is also president of Tru-Skin Franchise Development, LLC.

43. In 2016, Dr. Ladd was the principal founder of defendant, SkinCure, and is that company's Chief Medical Officer and one of its major equity holders. Dr. Ladd was the creator and instigator of the fraudulent scheme to bribe dermatologists for their unlawful referrals of DHS for Medicare patients—superficial radiation therapy services—and the willful presentation of fraudulent invoices to Medicare for payment through the formation of SkinCure and the creation of its SRT Turnkey Implementation Program. Dr. Ladd was mastermind of the unlawful scheme. Dr. Ladd knew, should have known or recklessly disregarded the fact that the SkinCure SRT Turnkey

Implementation Program violated *Stark*, the Anti-Kickback Statute and the False Claims Act.

Defendant, Steven B. Bonner

43. Defendant, Steven B. Bonner, an advisor to Chicago Pacific Founders and is a voting member of the Board of Directors of defendant, Pinnacle Dermatology. In his advisory role for Chicago Pacific and two other private equity firms, he advises those firms, serves as a board member, invests, and mentors the firms and the companies that they invest in. He received his Bachelor of Arts Degree in Political Science from Amherst College and his Juris Doctorate, Law Degree, from the William Mitchell College of Law. Bonner was President and Chief Executive Officer of The Cancers Treatment Centers of America from 1999 until February 2014. Bonner knew about, approved of, and voted to implement Pinnacle's unlawful contract with SkinCure. Such contract made Pinnacle a co-conspirator in the SRT Turnkey Implementation Program, which resulted in the knowing, unlawful referrals of Federal healthcare program patients to SkinCure in return for Pinnacle's receipt of unlawful kickbacks paid by SkinCure, all in violation of the *Stark* Law and the Anti-Kickback Statute. Bonner knew, should have known or recklessly disregarded the fact that the SkinCure SRT Turnkey Implementation Program violated *Stark*, the Anti-Kickback Statute and the False Claims Act.

Defendant, L. Peter Smith

44. Defendant, L. Peter Smith, has a long history as an executive, investor, entrepreneur in healthcare. He is a resident of a state other than the State of Tennessee, but at all material times he was doing business within the State of Tennessee and within the jurisdiction of this Court. He, along with defendant, Steven L. Scott, worked with defendant, Dr. Ladd, to create, develop and mastermind the fraudulent marketing scheme to defraud Medicare and violate the *Stark* Law, the

Anti-Kickback Statute and the False Claims Act. Smith knew, should have known or recklessly disregarded the fact that the SkinCure SRT Turnkey Implementation Program defrauded Medicare and violated *Stark*, the Anti-Kickback Statute and the False Claims Act.

Defendant, Steven L. Scott

45. Defendant, Steven L. Scott, is the Chief Operating Officer of defendant, SkinCure. He is a resident of a state other than the State of Tennessee, but at all material times he was doing business within the State of Tennessee and within the jurisdiction of this Court. He, along with defendant, L. Peter Smith, worked with defendant, Dr. Ladd, to create, develop and mastermind the fraudulent marketing scheme to defraud Medicare and violate the *Stark* Law, the Anti-Kickback Statute and the False Claims Act. Scott knew, should have known or recklessly disregarded the fact that the SkinCure SRT Turnkey Implementation Program defrauded Medicare and violated *Stark*, the Anti-Kickback Statute and the False Claims Act.

Defendant, CapX Partners, a/k/a, Accord CapX LLC

46. Founded in 1999, Defendant, CapX Partners, a/k/a Accord CapX LLC, is a private equity concern specializing in equipment finance, serving private equity sponsored and private held middle market companies, with offices in Boston, New York City and its main corporate offices located at 155 N. Wacker Drive, #1760, Chicago, Illinois 60606. CapX Partners touts itself as a hands-on lender, “thoroughly understanding your business and applying the right financing decisions is key to your success . . . and ours. . . . Our process involves an in-depth understanding of your strategic direction and organizational goals. We then quickly and efficiently conduct a comprehensive analysis of your opportunity and advise how we can help. The result: decisive actions, combined with flexible, creative, and customized solutions that can respond to even the most

complicated scenarios.”

47. In the fall of 2017, after “thoroughly understanding . . . [SkinCure’s business] . . . [and gaining] . . . an in depth understanding of [SkinCure’s] . . . strategic direction and organizational goals,” CapX partners agreed to loan SkinCure \$2,500,000 to enable it to perpetrate its fraudulent scheme to knowingly defraud Medicare and violate the *Stark* Law and the Anti-Kickback Statute. CapX Partners informed itself, and knew about SkinCure’s fraudulent SRT Turnkey Implementation Program and scheme, before lending it \$2,500,000. Confirming its own dirty hands in financing Skincure’s unlawful scheme, CapX’s press release about its investment in SkinCure stated, “CapX boosts SkinCure Oncology’s growth, preserving firm’s working capital while providing \$2.5 Million in growth financing.” When the loan closed in December 2017, CapX Partners became a co-conspirator with SkinCure in its violation of *Stark*, AKS and the False Claims Act. Relator is the original source of any publically disclosed information, if any, related to CapX Partners..

Defendant, Jeffrey S. Pfeffer

48. Defendant, Jeffrey S. Pfeffer, co-founded CapX Partners in 1999. His responsibilities with the firm include its management as Managing Partner. He has over three decades of small to mid-sized business finance experience. Pfeffer was involved with approving the CapX 2017, loan to SkinCure and in thoroughly understanding [SkinCure’s business and he gained] . . . an in depth understanding of [Skincure’s] strategic direction and organizational goals,” before approving and signing off on the CapX loan of \$2,500,000 to SkinCure in December 2017. Pfeffer either knew about, should have known about or recklessly disregarded, SkinCure’s pervasive plan to defraud, Federal and State healthcare programs by knowingly presenting them with false invoices for payment. Undoubtedly, defendants Pfeffer and CapX insisted that SkinCure pledge as security a

significant portion of its accounts receivable from Federal and State healthcare programs as a material term of their loan to SkinCure. Pfeffer either knew, should have known or recklessly disregarded that the SkinCure SRT Turnkey Implementation Program violated Stark, the Anti-Kickback Statute and the False Claims Act. SkinCure's unlawful plan had been under way for over a year at the time of the CapX, December 2017, loan. Pfeffer's reckless disregard for the law and his companies' \$2,500,000 to SkinCure, at his direction and with his approval, fueled the flames of SkinCure's fraud against the United States, the States and the American taxpayer. When the loan closed in December 2017, Pfeffer became a co-conspirator with SkinCure in its violation of *Stark*, AKS and the False Claims Act.

49. Pfeffer's interaction and involvement with SkinCure during the investigative phase and throughout the process leading to the loan closing in December 2017, was at the very least a civil misprison, perhaps more. The American Heritage Dictionary defines misprison as "mal-administration or neglect in preventing or reporting a crime." Paying bribes and kickbacks to dermatologists in exchange for their patient referrals is a crime. By reasonable inference, Pfeffer, and under the Doctrine of Respondeat Superior, CapX Partners, either knew about, should have known about or recklessly disregarded SkinCure's payment of bribes and kickbacks to fuel the business plan upon which SkinCure was founded—defraud Medicare. Relator is the original source of any publically disclosed information related to Pfeffer, if any, set forth herein.

Defendant, Fountain Partners, d/b/a, SeaCoast Capital

50. Defendant, Fountain Partners, ("Fountain"), was founded in 2006, in San Francisco, California with a mission to become "the most flexible and efficient source of equipment lease capital for growing businesses." It specialized in financing equipment leasing for venture, growth,

and expansion stage businesses. Fountain Partner's affiliate, SeaCoast Capital, loaned SkinCure \$30,000,000 in September 2019, to fuel a conflagration of false, fraudulent claim presentments to the United States and to the States. Such claim presentments violated *Stark*, AKS and the False Claims Act and corollary State Acts.

51. That defendant, Fountain, clearly knew about the \$30,000,000, loan and participated in it is evident by a reading between the lines of the following announcement of the loan on its website:

"SkinCure Oncology Closes \$30M Equity Financing

An early Fountain Partners' client, SkinCure Oncology announced a \$30M growth equity round with SeaCoast Capital on September 24, 2019. **SkinCure's turnkey model for the delivery of Image-guide Superficial Radiation Therapy (IG-SRT) has proven to be a great fit with quality focused dermatologists and Mohs surgeons.** By working with physician partners, SkinCure is able to bring cancer center level radiation therapy for the treatment of noon-melanoma skin cancers to local doctor's offices. **SkinCure Oncology has facilitated the treatment of more image guided superficial radiation therapy patients than any other group in the world."**

[emphasis added].

52. In describing its process about who to loan to and who not to loan to, Fountain has "created a process to make decisions efficiently and quickly. During our review and evaluation process we ask for specific business information, a description of the asset(s) being financed, and time with a member of management in order to deepen our understanding of the business model. Through our non-formulaic and non-checkbox approach to underwriting, we have the ability to understand both standard and complicated credit situations. . . ." If Fountain could understand the complicated credit situations, then they certainly had no problem seeing the SkinCure Program's

chief aim--to defraud the United States and the States.

53. From its website statement, Five reasonable inferences stand out about what Fountain knew about the SkinCure business model, including the following:

- (1) the existence and specific details of the SkinCure, SRT Turnkey Implementation Program;
- (2) SkinCure's bribes and kickbacks paid to dermatologists;
- (3) dermatologist's unlawful patient referrals to SkinCure;
- (4) extent of SkinCure's fraud against the Government and the States;
- (5) that SkinCure's revenue stream was funded by defrauding Medicare.

As to the last of the five points, what reasonable or prudent businessman would loan \$30,000,000 to a company less than three years old without knowing its principal revenue source. The reasonable inference is that Fountain and SeaCoast both knew about SkinCure's SRT Turnkey Implementation Program designed to defraud its most significant revenue source--Medicare. Before causing the loan of \$30,000,000 to SkinCure in September 2019, the principals of Fountain and Seacoast Capital knew, should have known or recklessly disregarded the fact that the SkinCure SRT Turnkey Implementation Program defrauded Medicare, violated *Stark*, the Anti-Kickback Statute and the False Claims Act. Relator is the original source of such information.

Defendant, Tom Carter

54. Defendant, Tom Carter, is founder, and managing partner of Fountain Partners. He had a principal role in analyzing and approving affiliated company, Seacoast's \$30,000,000 loan to SkinCure in September 2019. Carter knew, should have known or recklessly disregarded the fact that the SkinCure SRT Turnkey Implementation Program defrauded Medicare, violated *Stark*, the

Anti-Kickback Statute and the False Claims Act. Carter's interaction and involvement with SkinCure during the investigative process leading to the \$30,000,000 loan closing in September 2019, was at the very least a civil misprison.

Defendant, John Van Hooser

55. Defendant, John Van Hooser, is a managing partner of Fountain Partners. He had a principal role in analyzing and approving affiliated company, Seacoast's \$30,000,000 loan to SkinCure in September 2019. Van Hooser knew, should have known or recklessly disregarded the fact that the SkinCure SRT Turnkey Implementation Program defrauded Medicare, violated *Stark*, the Anti-Kickback Statute and the False Claims Act. Van Hooser's interaction and involvement with SkinCure during the investigative process leading to the \$30,000,000 loan closing in September 2019, was at the very least a civil misprison.

Defendant, Dermatology Practices And Co-conspirator Dermatologists

56. Each of the dermatology practices and co-conspirator dermatologists, set forth as defendants in the caption of this Verified Complaint, are similarly situated, having each signed on to the fraudulent SkinCure, SRT Turnkey Implementation Program. Rather than repeat the same, virtually identical operative facts for each separate defendant, such facts are set forth here and the name, address and contact information for each dermatology practice and dermatologist sued and listed in the caption is stated in Exhibit A which is incorporated by reference and made a specific part of this paragraph and this Verified Complaint. The operative facts, which each of the co-conspirator dermatologists share, are stated in paragraphs 57-58 immediately below.

57. The dermatologist defendants have each entered into the same unlawful business arrangement with defendant, SkinCure, which SkinCure calls its “SRT Turnkey Implementation Program.” SkinCure pays kickbacks and bribes to co-conspirator dermatologists in exchange for unlawful referrals of their Medicare patients for SkinCure to provide unauthorized DHS—superficial radiation therapy. SkinCure has never been a Medicare approved provider/supplier of superficial radiation therapy services. To induce such unlawful referrals, which violate *Stark*, SkinCure paid dermatologist defendants among other things the following bribes and kickbacks, at no charge: (1) a SRT-100-Vision, superficial radiation therapy machine, with a list price of \$495,000; (2) a board certified, radiation therapy technician, a SkinCure employee; (3) plans and construction costs to lead-line a room to safely accommodate the SRT Machine; (4) the administration and handling of all State registrations and filings for the SRT machine, (which included falsely registering the SkinCure-owned, SRT machine in the name of each dermatologist or their practice; (5) billing and collection services to co-conspirator dermatologists and their practices for all services performed on their Medicare patients using the SkinCure SRT machine; (these billings were all fraudulently done by SkinCure in the name of the co-conspirator dermatologists, or their practices, using the co-conspirator dermatologists’ Tax Identification Numbers--and most importantly--using their Medicare Provider/Supplier Billing Numbers), because at no material time was SkinCure a qualified Medicare Provider/Supplier for any item or service. And at no material time, did SkinCure possess a legitimate Medicare Provider/Supplier Billing Number; (6) but SkinCure’s “Crown Jewel” bribe and kickback was 40% of the Medicare reimbursement received, which was paid by SkinCure to each co-conspirator dermatologist.

58. Such bribes and kickbacks violated the Anti-Kickback Statute. Such bribes and kickbacks gave each co-conspirator dermatologist an unlawful financial interest in SkinCure. Their referrals of Medicare beneficiaries to SkinCure, were *Stark* Law violations. SkinCure, its conspirators and its co-conspirator dermatologists are each guilty of defrauding Medicare, violating *Stark*, AKS and the False Claims Act.

III. Jurisdiction And Venue

59. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the latter specially conferring jurisdiction on this Court for actions brought under 31 U.S.C. § § 3729 and 3730.

60. Personal jurisdiction and venue are proper in this District under 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), as defendants can be found, reside, transact business or otherwise engaged in the illegal conduct at issue within the District.

61. This action arises under the provisions of Title 31 U.S.C. § 3729 *et seq.*, more commonly known as the False Claims Act, which provides that the United States District Courts shall have exclusive jurisdiction over the actions brought under that Act.

62. Section 3732(a) of the Federal False Claims Act provides, “Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in any act proscribed by section 3729 occurred.”

63. Relator has filed this action within the 6 year statute of limitations under the False Claims Act. As discussed below, this action seeks recovery under the False Claims Act for violations

of the Federal *Stark* Law and the Anti-Kickback Statute for claims submitted by defendant, SkinCure, on behalf of its co-defendant, co-conspirators for reimbursement payments from Federal Healthcare Programs during the period 2016 continuing through the present and beyond. This action also seeks recovery for similar violations of the False Claims Acts of each of the State, Co-plaintiffs, during the same period.

64. Relator has complied with 31 U.S.C. § 3730(b)(2) by serving a copy of his written Disclosure Statement, containing substantially all of the material evidence and information in his possession, accompanied with substantial, material, supporting documents, upon the United State Attorney for the Middle District of Tennessee and upon the Attorney General of the United States, before filing his Verified Complaint. Relator, through his counsel, also has spoken by telephone with representatives of the United States Attorney's Office for the Middle District of Tennessee to provide notice to the Federal Government before submitting his Disclosure Statement or filing his Verified Complaint.

IV. Federal Stark Laws

A. Introduction

65. The Federal *Stark* Law “was enacted to address over-utilization, anti-competitive behavior, and other abuses of healthcare services that occur when physicians have financial relationships with certain ancillary entities to which they refer Medicare or Medicaid patients. . . . Physician financial arrangements may have anti-competitive effects to the extent that those relationships discourage other providers from entering a market in which patients are primarily referred to physician-owned entities or DHS entities that maintain generous compensation arrangements with physicians. . . . Anti-competitive behavior can increase program costs if the DHS

entities with which physicians have financial relationships are favored over others, more cost-efficient providers or providers that furnish higher quality care. . . . Over-utilization increases program costs because Medicare (or Medicaid) pays for more items or services than are medically necessary.”²⁰

B. The Stark Law Prohibits A Physician Making A Referral Of Designated Health Services To An Entity With Which They Have A Financial Interest

66. “The approach taken by Congress in enacting Section 1877 of the Act is preventive because it essentially prohibits many financial arrangements between physicians and entities providing DHS. . . . Specifically, Section 1877 of the Act imposes a blanket prohibition on the submission of Medicare Claims (and payment to the States of FFP under the Medicaid Program) for certain DHS when the service provider has a financial relationship with the referring physician, unless the financial relationship fits into one of several relatively specific exceptions.”²¹

67. When the *Stark* Laws were introduced in Congress in 1989, the sponsors of the law had correctly concluded that a physician’s referral of DHS to an entity with which the physician had a financial interest—including those entities paying the physicians bribes and kickbacks—corrupted the entire healthcare field. **“The evidence is clear that Americans are wasting millions of dollars each year for unnecessary tests and procedures . . . in other cases, the best and most convenient care is being denied.”**²² **“Unfortunately, one of the reasons some physicians perform**

20 69 Federal Register 16124 (March 26, 2004).

21 66 Federal Register 859.

22 135 CONG. REC. 4995 (Mar. 20, 1989) (Remarks of Rep. Stark (D.-Cal.)).

unnecessary procedures is that they earn a higher profit as a result. This is particularly true in the case of physicians who invest in facilities to which they can refer patients for specialty care.”²³ [emphasis added].

68. Congress enacted the *Stark* Law in two parts, commonly known as *Stark I* and *Stark II*. Enacted in 1989, *Stark I* applied to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992, by physicians with a prohibited financial interest with the clinical lab provider.²⁴

69. In 1993, Congress extended the *Stark* Law (*Stark II*) to referrals for ten additional designated health services (DHS).²⁵ Beginning January 1, 1995, *Stark II* applied to patient referrals by physicians with a prohibited financial relationship for the following ten additional “designated health services”: (1) inpatient and outpatient hospital services; (2) physical therapy; (3) occupational therapy; ((4) radiology; (5) radiation therapy (services and supplies); (6) durable medical equipment and supplies; (8) prosthetic orthotics and prosthetic devices and supplies; (9) outpatient prescription drugs; and (10) home health services.²⁶

70. In support of *Stark II*, Representative Stark, testifying before Congress, again made convincing remarks about the extent of corruption in healthcare in the United States and the pressing

23 135 CONG.REC. 12932 (June 21, 1989)(Remarks of Rep. Stark (D.-CAI)).

24 See Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6204.

25 See Omnibus Budget Reconciliation Act of 1993, P.L. 103-166 § 13562, Social Security Act Amendments of 1994, P.L. 103-432 § 152,

26 See 42 U.S.C. §1395nn(h)(6)

need for expanding the reach of the *Stark* Laws to stop the fraud. “Studies have shown that as many as 25% of procedures provided to patients in this country are not needed.”²⁷ **“Enough evidence has accumulated to show that buying and selling of referrals is costing all of us money and subjecting many of us to medical procedures and tests that we do not need. By enacting a comprehensive, across-the-board, ban on referrals, we can protect and improve consumers’ confidence in their physicians, as well as in the health care system generally.”**²⁸ [emphasis added].

71. The *Stark* Law broadly defines prohibited “financial relationships” to include “compensation arrangements” in which any “remuneration” is paid by a supplier of radiation therapy services or durable medical equipment, and related services—both listed DHS²⁹--to a referring physician “directly or indirectly, overtly or covertly, in cash or in kind.”³⁰

“The *Stark* Law broadly defines a prohibited ‘compensation arrangement’:

- (A) The term ‘compensation arrangement’ means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and any entity other than an arrangement involving only remuneration described in subparagraph (C).
- (B) The term ‘remuneration’ includes any remuneration, directly or

27 139 CONG. REC. E84 (January 6, 1993) (Remarks of Rep. Stark (D.-Cal.)).

28 139 CONG. REC. 346-47 (January 6, 1993) (Remarks of Rep. Stark (D.-Cal.)).

29 See 42 U.S.C. § 1395nn(h)(5)&(6).

30 See 42 U.S.C. § 1395nn(a)(2)(B), (h)(1); 42 C.F. R. § 411.354(c).

indirectly, overtly or covertly, in cash or in kind.”³¹

72. This language makes clear that Congress intended the definition of “financial relationship” to include any type of financial relationship in which physicians receive any remuneration of any kind from a supplier of DHS, directly, indirectly, overtly or covertly. And that includes any relationships where an entity furnishing DHS pays a physician kickbacks in any form. Paying kickbacks to induce: (1) referrals of patients or (2) DHS business, corrupts the integrity of every claim submitted as a result. Such kickback schemes violate the *Stark* and the Anti-Kickback Laws.

73. The *Stark* Law provides that if a physician has a financial relationship with a supplier of DHS, then:

“(A) The physician may not make a referral to the entity for the furnishing of [DHS] for which payment otherwise may be made under this subchapter,

and

(B) The entity may not present or cause to be presented a claim under the subchapter or bill to any individual, third party payor, or other entity for [DHS] furnished pursuant to a referral prohibited under subparagraph (A).”³²

74. In addition to prohibiting any supplier of DHS from submitting claims under these circumstances, the *Stark* Law also prohibits payments by Federal Healthcare Programs of such claims: “No payment may be made under this subchapter for a DHS which is provided in violation of

31 42 U.S.C. § 1395nn(h)(1).

32 42 U.S.C. § 1395nn(h)(1); see also: 42 C.F.R. § 411.353(a).

subsection (a)(1) of this section.”³³ If a provider of DHS submits prohibited claims and collects payments, the regulations implementing 42 U.S.C. § 1395nn require that any entity collecting payment for a healthcare service “performed under a prohibited referral, must refund all collected amounts on a timely basis.”³⁴

C. The Stark Law’s Broad Definition Of Referral

75. The *Stark* Law defines “referral” as “the request or establishment of a plan of care by a physician, which includes the provisions of designated health services.”³⁵ In a Sixth Circuit case, involving an alleged violation of the Anti-Kickback Statute, the Court analyzed the meaning of the term “induce” or “inducement.”³⁶ The Court’s analysis of the terms is applicable to *Stark* Law. The term “induce” is “the necessary intent ‘to lead or move by influence or persuasion.’”³⁷ Although the term “induce” applies to the party offering or paying remuneration, it sheds light on . . . the recipient of the remuneration, implying that the recipient must be duly induced or ‘move[d]’ An important aspect of inducement is that the remuneration be directed towards an individual or entity ‘in position to generate Federal healthcare program business.’”³⁸

33 42 U.S.C. § 1395nn(g)(1); see also: 42 C.F.R. § 411.353(b)(c)&(d).

34 42 C.F.R. § 353.

35 42 U.S.C. § 1395nn(h)(5)(A).

36 *Jones-McNamara v. Holzer Health Systems*, 630 Fed. Appx. 394, 401 (6th Cir. 2015) (Citing and relying upon OIG Anti-Kickback Provisions, 56 Fed. Reg. 35938, 35952 (July 29, 1991)).

37 *Id.* at 401.

38 *Id.* at 401

76. The accompanying regulations applying the *Stark* Law also broadly define referral as, among other things, “a request by a physician that includes the provision of any designated health service for which the payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of a designated health service, or the certifying or re-certifying of the need for such a designated health service”³⁹ A referring physician is defined in the same regulation as “a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals to another person or entity.”⁴⁰

77. As previously discussed, the *Stark* Law broadly defines prohibited “financial relationships” to include any “compensation” paid directly or indirectly to a referring physician. The *Stark* Law’s exceptions identify specific transactions that will not trigger its referral and billing prohibitions. These include certain general exceptions for Physician Services and In-office Ancillary Services. A physician must meet specific requirements to qualify for these general exceptions.⁴¹ Additionally, there are certain exceptions, specifically related to compensation arrangements.⁴² To avoid the referral and billing prohibitions in the *Stark* Law, an entity supplying designated health services must satisfy one of the exceptions.

78. Not a single general exception under *Stark* or a *Stark* exception related to

39 42 C.F.R. § 411.351.

40 42 C.F.R. § 411.351.

41 *Id.*

42 42 C.F.R. § 411.357.

compensation arrangements,⁴³ applies to the facts of this present case to allow defendants to avoid *Stark*'s referral and billing prohibitions.

79. Once Relator or the Government has established proof of each element of a violation under the Act, the burden shifts to the defendant to prove that the conduct was protected by an exception. If no exception applies to a *Stark* violation, then all such referrals from the referring physician to the DHS entity are prohibited. If the prohibited referrals have been reimbursed by the Government or the States, then the physician and the DHS entity, together with any co-conspirators in the scheme, are liable to repay the Government and the States, the amounts they reimbursed—trebled—under the Federal False Claims Act and most State False Claims Acts.⁴⁴

80. Simply stated, defendants cannot meet this burden of proof.

D. Review Of Possible Exceptions Under *Stark* And Why They Do Not Apply To Defendants' Unlawful Conduct

1. Possible General Exceptions Under 42 C.F.R. § 411.355

(a) Physicians Services § 411.355(a)(1)

81. This possible exception to *Stark*'s referral prohibition deals with physician services provided personally by another physician member of the physician's group practice or under such a physician's supervision.⁴⁵ Supervision services provided under this section must "[comply] with all other applicable Medicare payment and coverage rules for the physician services."⁴⁶ This exception

43 42 C.F.R. § 411.357.

44 42 C.F.R. § 353; 31 U.S.C. § 3729(a)(1).

45 42 C.F.R. § 355(a)(1)(i)&(ii).

46 *Id.*

does not apply because the DHS provided by SkinCure was not provided by “another physician” in a single one of the co-conspirator dermatology group defendants or physicians with which SkinCure contracted. The superficial radiation therapy services—DHS—was provided by SkinCure using the Skin/Cure SRT machine, operated by the SkinCure technician. SkinCure violated Medicare payment and coverage rules because such services were procured by SkinCure’s bribes and kickbacks paid to the Dermatologist defendants, which violated AKS. And, at no material time, was SkinCure an approved Medicare provider/supplier of superficial radiation therapy services. Moreover, SkinCure was never a legitimate Medicare billing agent for its co-conspirator dermatologists. Therefore, the Physician Services exception does not apply to save the defendants’ illegal referrals of DHS business to SkinCure.

(b) In-office Ancillary Services § 411.355(b)

82. This exception requires that the ancillary services can be provided by “An individual who is supervised by the referring physician or . . . [if a group practice] . . . by another physician in the group practice provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.”⁴⁷ Billing for the ancillary services by an independent third party billing company acting as an agent for a physician group practice must comply with multiple regulations⁴⁸ including 42 C.F.R. § 424.73(b)(3), which requires the following:

“Medicare may pay an agent who furnishes billing and collection services to the provider if the following conditions are met:

- i. The agent receives the payment under an agency agreement with the

⁴⁷ 42 C.F.R. § 355(b)(1)(iii).

⁴⁸ 42 C.F.R. §§ 424.73(b)(3), 424.80(a)&(b)(5).

provider;

- ii. The agent's compensation is not related in any way to the dollar amounts billed or collected;
- iii. The agent's compensation is not dependent upon the actual collection of payment;
- iv. The agent acts under payment disposition instructions that the provider may modify or revoke at any time; and
- v. The agent in receiving the payment acts only on behalf of the provider."

83. Once again, SkinCure's superficial radiation therapy services, which do not even qualify as in-office ancillary services, were provided using the Skin/Cure SRT machine, operated by the SkinCure technician. Such services violated AKS because they were procured by SkinCure's bribes and kickbacks paid to co-conspirator dermatologists and as previously stated, SkinCure was not a Medicare approved provider/supplier of such DHS. The billing requirements for an independent agent of the physician to bill for the ancillary services were also not met. SkinCure, by contract, was the dermatologist's purported agent for billing and collection. SkinCure's compensation was directly related to the amounts it collected on behalf of its dermatology co-conspirators and whether or not collection actually occurred. SkinCure received 60% of the amounts it collected and was, therefore, acting on its own behalf. The billing instructions to SkinCure were binding and irrevocable on the co-conspirator dermatologists for two years except under limited circumstances. Therefore, the In-office Ancillary Services exception does not apply to save the defendants' illegal referrals of DHS business to SkinCure.

- 2. **Possible Exceptions Related To Compensation Arrangements Under 42 C.F.R. § 411.357**
 - (a) **A Legitimate Durable Medical Equipment Lease Exception Must Satisfy Four Material Requirements § 411.357(b)**

84. Defendants could speciously argue that they somehow qualify for this exception. But the SRT Turnkey Implementation Program was not a lease—it was the payment of bribes and kickbacks to induce unlawful referrals of DHS—superficial radiation therapy services—from co-conspirator dermatologists. The rental or lease of durable medical equipment is a designated healthcare service (DHS) as set forth in the *Stark Law*.⁴⁹ But, a physician may not lease durable medical equipment from a DHS entity unless at least the five following material preconditions are met:

(1) The equipment leased does not exceed that which is reasonably necessary for the legitimate business purposes of the lease *and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.*⁵⁰

(2) The rental charges over the terms of the lease are in writing and set in advance and signed by the parties.⁵¹

(3) *The rental charges . . . are consistent with fair market value, and are not determined—*

(i) *In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or*

(ii) *Using a formula based on—*

(A) *A percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed on or business generated through the use of the equipment. . . .*

49 42 U.S.C. § 1395nn(h)(6).

50 42 C.F.R. § 411.357(b)(2).

51 42 C.F.R. § 411.357(b)(2).

(4) *The lease arrangement would be commercially
reasonable even if no referrals were made between the parties.*

[emphasis added].

85. Fair market value “means the value in arm’s-length transactions, consistent with the general market value, which means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers. . . .”⁵² Even the proposed new Sprint Regulations equate fair market value with general market value, which they define as meaning “the price that assets or services would bring as a result of *bona fide* bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service agreement. . . .”⁵³ As will be seen, the amount which SkinCure received for the lease of the SRT machine to its co-conspirator dermatologists, grossly exceeded a fair market value lease. Such defendants realized obscene profits on their transaction at the expense of the Government, the States and the American tax payer.

86. The Durable Medical Equipment Lease exception to application of the *Stark* prohibition against a physician referral does not apply in the present case to any purported lease SkinCure may claim to have made, if any, to a co-conspirator dermatologist for the following reasons:

- (1) Dominion, control and operation of the leased SkinCure owned, SRT machine was maintained by the lessor, SkinCure, whose employee, radiation therapy technician, operated and controlled the SRT machine at all material times;⁵⁴
- (2) SkinCure’s purported rental charges for the SRT machine vastly exceeded fair market value for the lease of such a machine The SkinCure rental charge was

52 42 C.F.R. § 411.351.

53 Proposed Sprint Regulation at 42 C.F.R. § 411.351.

54 42 C.F.R. § 411.357(b)(2).

not consistent with fair market value, which Sensus, the manufacturer of the SRT-100-Vision machine stated in its promotional literature was \$6000/month.⁵⁵

- (3) Purported rental charges took into account the value and volume of the referral of the business generated, using a percentage of the revenue generated from the use of the SRT machine to determine the purported rental charge;
- (4) The purported lease arrangement of the SRT by SkinCure to the dermatology co-conspirators was not commercially reasonable.

87. Therefore, the Durable Medical Equipment Lease exception, even if a lease exists, does not apply to save the defendant, co-conspirator, dermatologists' illegal referrals of DHS business to SkinCure.

(b) **A Legitimate Personal Services Arrangement Exception Between A Referring Physician And An Entity Furnishing DHS Must Satisfy At Least Five Material Requirements § 411.357(d)**

88. A legitimate personal services arrangement exception between a referring physician and a supplier of DHS must satisfy as least five material requirements including, among others, the following:

- (1) The aggregate services covered by the arrangement to not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s);
- (2) The compensation to be paid over the term of each arrangement is set in advance;
- (3) The compensation does not exceed fair market value;
- (4) The compensation to be paid . . . is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the

⁵⁵ 42 C.F.R. § 411.357(b)(4); See also, Exhibit D, Sensus Reimbursement Table.

parties;

(5) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.⁵⁶

[emphasis added].

89. This possible exception to the *Stark* referral prohibition does not apply in the present case for the following reasons:

- (1) The compensation for personal services rendered by SkinCure to its co-conspirator dermatologists was variable depending on the value and volume of the referrals and of the business generated;
- (2) The compensation paid to SkinCure was grossly in excess of the fair market value of the services rendered;
- (3) The services rendered by SkinCure were procured through its payment of kickbacks to its co-conspirator dermatologists, which violated the Anti-Kickback Statute.

90. Therefore, the Personal Services Arrangement exception does not apply to save the defendant, dermatologists' illegal referrals of DHS business to SkinCure nor does it save the related unlawful billing arrangements.

E. **The Prohibition Of Assignment Of Claims By Providers**
42 C.F.R. § 424.57(a)

91. Under its rules and regulations, Medicare will generally not pay amounts that are due a provider, to any other person under assignment, power of attorney or any other direct payment

⁵⁶ 42 C.F.R. § 411.357(b)(iii)(v)&(vi).

arrangement.⁵⁷ However, Medicare may pay an agent who furnishes billing and collection services if the following conditions are met:

- (1) The agent receives the payment under an agency agreement with the provider;
- (2) The agent's compensation is not related in any way to the dollar amounts billed or collected;
- (3) The agent's compensation is not dependent upon the actual collection of payment;
- (4) The agent acts under payment disposition instructions that the provider may modify or revoke at any time; and
- (5) The agent in receiving the payment acts only on behalf of the provider.

92. SkinCure's contracts with its co-conspirator dermatologists did not meet the conditions necessary to allow lawful assignment of the dermatologists' claims for payment from Medicare to SkinCure for the following reasons: (1) SkinCure's compensation was directly related to the amounts it collected on behalf of its co-conspirator dermatologists; (2) SkinCure's compensation was directly related to whether or not collection actually occurred; (3) SkinCure received 60% of the amounts it collected from Medicare—the more it collected, the more it received; (4) SkinCure was most definitely acting on its own behalf in such collection efforts and not acting "only on behalf of the provider;" and finally, (5) the billing instructions to SkinCure were binding and irrevocable on the co-conspirator dermatologists for two years except under limited circumstances. Therefore, the assignment by every co-conspirator dermatologist of its Medicare claims to SkinCure was unlawful. Neither Medicare nor any Federal or State healthcare program would have paid SkinCure, as purported agent, nor its co-

⁵⁷ 42 C.F.R. § 424.357(a).

conspirator dermatologists for the unlawful claims for DHS submitted to Medicare and other Federal and State healthcare programs for payment had such programs known the truth about the unlawful assignments and the false claims for payment being presented by SkinCure.

V. Introduction To The Anti-Kickback Statute, (AKS)

A. Liability Under The Anti-Kickback Statute 42 U.S.C. § 1320a-7b(b)

93. The Anti-Kickback Statute, (AKS), prohibits any person or entity from offering, making or accepting payment to induce or reward any person for referring, recommending or arranging for federally funded healthcare services, including services provided under the Medicare, Medicaid and TRICARE healthcare programs.⁵⁸ The Anti-Kickback Statute prohibits a provider of DHS from offering or paying “any remuneration . . . directly, indirectly, overtly or covertly, in cash or in kind to any person to induce such person to . . . refer an individual for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal healthcare program.”⁵⁹ The Sixth Circuit has held that the AKS is to be broadly interpreted, and so long as one purpose of the remuneration is to induce referrals, a violation may be found.⁶⁰

94. The Sixth Circuit has also held that a kickback violation requires remuneration paid (1) to a person or entity in position to refer Federal healthcare program patients, and (2) that could reasonably induce the person or entity to refer such patients.⁶¹ An intent to induce referrals has been

58 42 U.S.C. § 1320a-7b(b).

59 *Id.*

60 *United States v. Millennium Radiology, Inc.*, 2014 U.S. Dist. LEXIS 138549, at *18 (S.D. Ohio Sept. 30, 2014).

61 *Jones-McNamara v. Holzer Health Systems*, 630 Fed. Appx. 394, 400-01 (6th Cir. 2015).

found to mean “an intent to gain influence over the reason or judgment of . . . physicians.”⁶² The falsity of a claim is determined at the time the claim is submitted to a Federal healthcare program for payment.⁶³ If a healthcare provider violates its continuing duty to comply with Medicare regulations on which payment is conditioned, the provider for its claims submitted to Medicare for payment is liable under the False Claims Act.⁶⁴

B. Review Of AKS Safe Harbors That Do Not Apply To Defendants’ Unlawful Conduct 42 C.F.R. § 1001.952

1. The Equipment Rental Safe Harbor Does Not Apply Unless Each Of Six Primary Standards Is Met 42 C.F.R. § 1001.952(c)

95. As used in Section 1128B of the Anti-Kickback Statute, “remuneration” does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met:

- (1) The lease agreement is set out in writing and signed by the parties;
- (2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease;
- (3) [Provision for periodic rental - not applicable];
- (4) The term of the lease is for not less than one year;
- (5) **The aggregate rental charge is set in advance, is consistent with fair market value, in an arms-length transaction and is not determined in a manner that takes into**

62 *United States ex rel. Wilkens v. Medtronic, Inc.*, 2016 U.S. Dist. LEXIS 2993167, at *7(D. Mass. May 23, 2016) (citing *United States v. McClatchey*, 217 F. 3d 832, 834 (10th Cir. 2000)).

63 *United States v. Southland Mgm’t Corp.*, 288 F. 3d 665, 681 (5th Cir. 2002).

64 *United States ex rel. Augustine v. Century Health Services*, 289 F. 3d 409, 415 (6th Cir. 2002).

account the volume or value of any referrals of business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal healthcare programs;

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable purpose of the rental. . . .⁶⁵

[emphasis added].

96. As with the Durable Medical Equipment Lease exception under *Stark*, the corollary Equipment Rental Safe Harbor under AKS does not apply for the same reasons as follows:

- (1) Dominion, control and operation of the leased SRT machine was maintained by the purported lessor, SkinCure, whose employee, superficial radiation therapy technician, operated and controlled the SRT machine at all material times;
- (2) Purported rental charges for the SRT machine vastly exceeded fair market value for the lease of such a machine;
- (3) Purported rental charges took into account the value and volume of the referral of the business generated, using a percentage of the revenue generated from the use of the SRT machine to determine the rental charge;
- (4) The purported lease arrangement of the SRT by SkinCure to the dermatology co-conspirators was not commercially reasonable.

Any reliance defendants may make on the Durable Medical Equipment Lease “Safe Harbor” is simply misplaced.

2. **The Personal Services And Management Safe Harbor Does Not Apply Unless Each Of Six Primary Standards Is Met 42 C.F.R. § 1001.952(d)**

97. As used in Section 1128B of the Anti-Kickback Statute, “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met:

⁶⁵ 42 C.F.R. § 1001.952(c).

- (1) The agency agreement is set out in writing and signed by the parties;
- (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent;
- (3) [Provision for part time services - not applicable];
- (4) The term of the agreement is for not less than one year;
- (5) **The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value, in an arms-length transaction and is not determined in a manner that takes into account the volume or value of any referrals of business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal healthcare programs;**
- (6) **The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.**
- (7) **The aggregate services contracted for do not exceed that which is reasonably necessary to accomplish the commercially reasonable purpose of the rental.**

...⁶⁶

[emphasis added].

98. For the reasons previously stated, in paragraphs 81-83 herein, this “Safe Harbor” does not apply to save defendants’ unlawful conduct. Additionally, defendants through their fraud and conspiracy were promoting “a business arrangement or other activity that violates . . . State or Federal law . . . [or both]”—violations that makes the “Safe Harbor” inapplicable. Defendants conspired to use, make and present false X-ray equipment registration documents to various state agencies throughout the United States to coverup the true ownership of the SRT-100-Vision machines providing DHS to Medicare beneficiaries and to misrepresent the truthful identity of the “Radiation Safety Officers or

66 42 C.F.R. § 1001.952(d).

person in charge of X-ray equipment.”

3. The Referral Services Safe Harbor Does Not Apply Unless Each Of Four Primary Standards Is Met 42 C.F.R. § 1001.952(f)

99. As used in Section 1128B of the Anti-Kickback Statute, “remuneration” does not include any payment or exchange of anything of value between an individual or entity . . . and another entity serving as a referral service . . . , as long as all of the following four standards are met:

(1) [An exclusion standard not applicable];

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume of value of any referrals to or business otherwise generated by either party for the referral service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal healthcare programs.

(3) [An exclusion standard not applicable];

(4) [An exclusion standard not applicable].

[emphasis added].

100. For the same reasons previously stated, in paragraphs 81-83 herein, this “Safe Harbor” does not apply to save defendants’ unlawful conduct from the penalties and liabilities that flow for their violation of the Anti-Kickback Statute.

4. The Referral Arrangement For Specialty Services Safe Harbor Does Not Apply Unless Each Of Four Primary Standards Is Met 42, C.F.R. § 1001.952(s)

101. As used in Section 1128B of the Anti-Kickback Statute, “remuneration” does not include any exchange of value among individuals or entities . . . Where one party agrees to refer a patient to the other party for the provision of specialty medical service payable in whole or

in part under Medicare, Medicaid or any other Federal healthcare program in return for an agreement on the part of the other party to refer that patient back at a mutually agreed time upon time or circumstance as long as the following four conditions standards are met;

- (1) [An exclusion standard not applicable];**
- (2) [An exclusion standard not applicable];**
- (3) The parties receive no payment from each other for the referral and do not share or split a global fee from any Federal healthcare program in connection with the referred patient;**
- (4) Unless both parties belong to the same group practice as defined in paragraph (p) of this section, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient compensating the parties for the services they each have furnished to the patient.**

[emphasis added].

102. This “Safe Harbor” does not apply because SkinCure and its co-conspirator dermatologists received payments from each other for the referral of non-melanoma skin cancer patients and they “split a global fee from . . . [a] . . . Federal healthcare program in connection with the referred patient.” And SkinCure and the co-conspirator dermatologists do not belong to the same group practice. SkinCure is not a lawful member of any medical practice group.

VI. The Fraud And Conspiracy of Defendants To Willfully Violate Stark, AKS And The False Claims Act

A. Brief Summary Of Defendants' Fraud And Conspiracy

103. SkinCure paid bribes and kickbacks to co-conspirator dermatologists to induce them to make unlawful referrals of their patients to SkinCure for superficial radiation therapy services, (DHS) provided by SkinCure in the dermatologist's clinic using a SkinCure provided SRT machine operated by a SkinCure employee. The kickbacks were unlawful under AKS and gave the dermatologists a financial interest in SkinCure, which violated the *Stark* Law. No Safe Harbor applied to legitimize SkinCure's payment of unlawful kickbacks. No *Stark* exception applied to legitimize the co-conspirator dermatologists' unlawful referrals.

104. Other defendants, principally private equity investors, joined the SkinCure conspiracy. CapX Partners, and its specific partners, reviewed and studied the SkinCure marketing plan including its "SRT Turnkey Implementation Program" in December 2017, before loaning it \$2.5 Million Dollars to fuel its fraud against Federal and State healthcare programs. Chicago Pacific Founders and their partners, Tolan, Hatcher, Varnier and Bonner, who each took an active, hands-on role in running the business affairs of defendant, Pinnacle, conspired with SkinCure and the dermatologists to violate *Stark*, the Anti-Kickback Statute and the False Claims Act. Since March 2017, when these private equity investors began pumping millions of dollars into Pinnacle they placed themselves as the controlling votes on the Pinnacle Board, they hijacked control of the company and untied it from its medical moorings and relaunched it as a for profit dreadnought. Then, when SkinCure showed up at Pinnacle in August 2019, with its fraudulent, "SRT Turnkey Implementation Program," with its "Pot of Gold" revenue potential, the Pinnacle brain trust, especially its private equity investors, could not

race fast enough to sign on to the SkinCure conspiracy to defraud the Government and the States. Fountain Partners d/b/a Seacoast Capital joined the fraud in September 2019, with its \$30,000,000 loan to exponentially expand SkinCure's fraud against Medicare.

105. Every named defendant conspired with SkinCure and every other defendant to violate *Stark*, the Anti-Kickback Statute and the False Claims Act.

B. The OIG Special Advisory Bulletin Of 2003 Warning About Schemes Just Like Defendants' Scheme Of Fraud And Conspiracy

106. For over 30 years, the Office of Inspector General has been warning business and healthcare officials about fraudulent schemes involving complex contractual arrangements between physicians and providers of DHS that violate *Stark* and AKS and defraud Federal Healthcare programs. In 2003, the OIG Special Advisory Bulletin entitled, "Contractual Joint Ventures" warned of almost the precise factual scenario presented by the SkinCure fraudulent scheme.⁶⁷ OIG warned that "kickbacks are harmful because they can (1) distort medical decision-making, (2) cause overutilization, (3) increase costs to the federal healthcare programs, (4) and result in unfair competition by freezing out competitors unwilling to pay kickbacks."⁶⁸

107. The opinion focused on "questionable contractual arrangements where the healthcare provider in one line of business, (the "Owner"), expands into a related healthcare business by contracting with an existing provider, (the "Manager/Supplier"), of a related service, [DHS for example], to provide the new service to the Owner's existing patient population, including federal

⁶⁷ Exhibit E, OIG Advisory Opinion entitled, "Contractual Joint Ventures," which refers to an earlier OIG Special Fraud Alert issued on December 19, 1989. 59 FR 65372.

⁶⁸ *Id.*

healthcare program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return profits of the business as remuneration for its federal healthcare program referrals.”⁶⁹

108. “The problematic arrangements typically exhibit certain common elements:

(a) The Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner’s existing business. . . . Typically, the new business [line] primarily serves the Owner’s existing patient base.

(b) The Owner neither operates the new business nor commits substantial financial, capital or human resources to the new venture. Instead, it contracts out substantially all the operations of the new business. The Manager/Supplier typically agrees to provide not only management services, but also a range of other services, such as inventory necessary to run the business, office and health care personnel, billing support and space. While the Manager/Supplier essentially operates the business, the billings of insurers and patients [and Federal State healthcare programs] is done in the name of the Owner. . . . While the contract terms of these arrangements may appear to place the Owner at financial risk, the Owner’s business risk is minimal because of the Owner’s ability to influence substantial referrals to the new business.

(c) The Manager/Supplier is an established provider of the same services as the Owner’s new line of business. In other words, absent the contractual arrangement, the Manager/Supplier would be a competitor of the new line of business. . . .

(d) The Owner and the Manager/Supplier share in the economic benefit of the Owner’s new business. The

69 *Id.*

Manager/Supplier takes its share in the form of payments under the various contract(s) with the Owner; the Owner receives its share in the form of the residual profit from the new business.

(e) Aggregate payments to the Manager/Supplier vary typically with the value or volume of business generated for the new business by the Owner. . . . In other words, the aggregate payments to the Manager/Owner will vary with referral from the Owner. Likewise, the Owner's payments. . . also vary based on the Owner's referrals to the new business. Through these contractual payments, the parties are able to share profits of the new line of business."⁷⁰

109. The new business line between an Owner and a Manager/Supplier under these circumstances is a joint venture; and provision of items or services to a joint venture by a participant in the venture is not an "arm's length" transaction. OIG has specifically stated that it has never intended to protect business arrangements between a physician and a supplier of items or services when they enter into a collusive arrangement and seek to share profits with each other.⁷¹

110. The following characteristics are those of a "Suspect" Contractual Joint Venture:

(a) **New Line of Business.** The Owner typically seeks to expand into a health care service that can be provided to the Owner's existing patients.

(b) **Captive Referral Base.** The newly-created business predominantly or exclusively serves the Owner's existing patient base. . . . The Owner does not intend to expand the business to serve new customers. . . ."

(c) **Scope of Services Provided By The Manager/Supplier.** The Manager/Supplier provides all or many of the following key services:

- day-to-day management;
- billing services;
- equipment;

⁷⁰ *Id.*

⁷¹ *Id.* See also 56 FR35977 (July 29, 1991).

- personnel and related services;
- office space;
- training;
- health care items, supplies and services.

(d) **Remuneration**. The practical effect of the arrangement, viewed in its entirety, is to provide the Owner the opportunity to bill insurers, patients and Federal and State healthcare programs for business otherwise provided by the Manager/Supplier. The remuneration from the venture to the Owner and to the Manager/Supplier takes into account the value and volume of business the Owner generates.

(e) **Exclusivity**. The parties may agree to a non-compete agreement.

These characteristics of a typical unlawful scheme outlined by OIG in its Special Advisory Bulletin in 2003, substantially describes the characteristics of SkinCure's unlawful scheme, which it entered into with Pinnacle and other dermatology defendants with the intended purpose of presenting false claims to Federal and State healthcare programs for payment.

C. **Defendants' Fraud And Conspiracy**

1. **Introduction And Background Information**

111. Baby Boomers—the sun bunnies of the decades of the 50s and 60s—are now moving through the healthcare system in the United States with most age 65 or older and Medicare beneficiaries. They are also increasingly in need of dermatology care because of the unwise sun exposure of their youth. Thus the demand for Dermatology services is rapidly expanding particularly for this demographic group, which is presenting in ever greater numbers for treatment of melanoma and non-melanoma skin cancers. In fact, about 70% of all non-melanoma skin cancer presentations are in patients 65 years of age or older and thus Medicare beneficiaries. The gold standard for treating non-melanoma skin cancers, the majority of skin cancers, is Mohs Surgery, which is microscopic

surgery where the surgeon surgically removes a thin top layer of the cancerous lesion, sends that layer to an on-site lab to be frozen so the surgeon can then examine it, in office, under the microscope. If cancer still exists, the surgeon removes another layer, and the process begins again until cancer cells are no longer present. Mohs Surgery has proven cost effective and successful and is the medical standard of care for treating the vast majority of non-melanoma basal cell and squamous cell carcinomas.

112. There is, however, a small subset of these cancers, which is better treated by superficial radiation therapy, (SRT). This subset is a small percentage of basal cell and squamous cell cancer presentations. The possible indications for SRT treatment over Mohs Surgery are: (1) location of the lesions—the nose, ears and face and areas of the body with poor blood flow could suggest SRT treatment; (2) patient co-morbidities such as diabetes, heart conditions or any medical conditions that make patients poor candidates for surgery or recovery from surgery would also suggest SRT treatment. But the vast majority of patients presenting with basal cell or squamous cell carcinoma for treatment, are best treated with--gold standard--Mohs Surgery.

113. Recently, with the development of more and better superficial radiation therapy machines, which have gained approval for medical use by the Food & Drug Administration, Medicare reimbursement for these new SRT machines has sky-rocketed. For example, a physician charging for SRT treatment could receive Medicare reimbursement from \$7000 to \$10,000 perhaps more, while reimbursement for Mohs Surgery is about \$1500. And significantly, most dermatologists are not Mohs Surgeons. Some dermatologists, business and private equity profiteers have recognized that by shifting the treatment for non-melanoma skin cancers away from the long standing, gold standard, Mohs Surgery to “better paying” SRT treatment, they can realize huge profits.

2. The Law Of Conspiracy

114. Simply stated, a civil conspiracy is “An agreement between two or more persons to commit an unlawful act that causes damage to a person or property.”⁷² The general Federal conspiracy statute creates an offense “[i]f two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose.”⁷³ “To conspire to defraud the United States means primarily to cheat the Government out of property or money, but it also means to interfere or obstruct one of its lawful governmental functions by deceit, craft or trickery, or at least by means that are dishonest.”⁷⁴ Section 371 reaches “any conspiracy for the purpose of impairing, obstructing or defeating the lawful function of any department of Government.”⁷⁵

115. Although the essence of conspiracy is agreement, an express agreement is not necessary to prove a civil conspiracy.⁷⁶ Tacit understanding, created and executed over time, is enough to constitute an agreement even absent personal communication.⁷⁷ Once the existence of a conspiracy has been established, slight evidence is needed to connect a particular participant to the conspiracy.

72 BLACK’S LAW DICTIONARY 375 (10th ed. 2014).

73 18 U.S.C. § 371

74 *Hammerschmidt v. United States*, 265 U.S. 182, 188 (1924).

75 *Tanner v. United States*, 483 U.S. 107, 128 (1987).

76 *Hobson v. Wilson*, 737 F. 2d 1, 51 (D.C. Cir. 1984).

77 *Direct Sales Co. v. United States*, 319 U. S. 703,714, 63 S. Ct. 1265, 1271 87 L. Ed. 1674 (1943).

⁷⁸ Each conspirator is liable for the overt acts committed by any member of the conspiracy, even if the defendant did not personally commit the acts.⁷⁹ Each conspirator need not have known all of the details of the illegal plan or all of the participants involved.⁸⁰ A conspirator may join at any point in the progress of the conspiracy and be held responsible for all that may be or has been done.⁸¹ “A conspiracy, once established, is presumed to continue until the contrary is established.”⁸² Under the False Claims Act, defendants are jointly and severally liable for damages assessed by a trier of fact.

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3. Inception Of Defendants’ Fraud And Conspiracy

116. In 2016, defendant, Dr. Daniel Ladd, together with his two co-conspirators and founders of SkinCure, defendants, Steven Scott and L. Peter Smith, master-minded an unlawful program to defraud Federal and State healthcare programs by presenting fraudulent bills for payment to such programs that were based on kickbacks and unlawful referrals, which violated *Stark* and AKS. The essential elements of SkinCure’s unlawful program—the SRT Turnkey Implementation Program—are the following:

⁷⁸ *United States v. Braasch*, 505 F. 2d 139, 148 (7th Cir. 1974).

⁷⁹ *Poliafico v. United States*, 237 F. 2d 97, 104 (6th Cir. 1956).

⁸⁰ *Hooks v. Hooks*, 771 F. 2d 935, 944 (6th Cir. 1985).

⁸¹ *Braverman v. United States*, 125 F. 2d 283, 286 (6th Cir. 1942); rev’d on other grounds 317 U.S. 49, 63 S. Ct. 99, 87 L.Ed. 23 (1942).

⁸² *Hyde v. United States*, 225 U.S. 347, 32 S. Ct. 793, 56 L. Ed. 1114 (1912).

⁸³ *United States v. Stevens*, 605 F. Supp. Ed 863, 867 (W.D. Ky. 2008); *United States v. Augustine Century Health Services*, 136 F. Supp. 2d 876, 895 (M.D. Tenn. 2000); aff’d 289 F. 3d 409 (6th Cir. 2002).

- (1) Enter into confidential, secret contracts with dermatologists by which SkinCure would provide the dermatologists, at no charge, with:
 - (i) a \$495,000, Sensus SRT-100-Vision superficial radiation machine, with its ownership remaining with SkinCure;
 - (ii) a board certified radiation therapy technician, a SkinCure employee, who would operate the machine in the dermatologist's office;
 - (iii) plans and construction of a lead-lined room to safely accommodate the operation of the SRT machine;
 - (iv) State radiation registrations and filings;
 - (v) billing and collection services in the name of the dermatology practice;
 - (vi) a medical physicist; and,
 - (vii) an account manager.
- (2) SkinCure would have complete access to the dermatologist's patient base 70% of which were Medicare beneficiaries .
- (3) In return for everything provided to the dermatologist by SkinCure, they would split the reimbursements and fees generated -- 70% of which were paid by Medicare -- from the operation of the SRT machine in the dermatologist's office by the SkinCure employee to treat the dermatologist's patients: 60% of the reimbursement paid to SkinCure; 40% to the dermatologist.
- (4) There were mutual non-compete and confidentiality provisions in the contract.
- (5) This arrangement included reimbursements received for treatment of beneficiaries of Federal and State healthcare programs.

4. Dermatologists Join The Fraud As Co-Conspirators

117. This was an incredibly sweet deal for co-conspirator dermatologists but particularly for those who were not also Mohs Surgeons. For them, instead of sending their non-melanoma cancer patients out-of-office to a Mohs Surgeon, for which the referring dermatologist received no part of

the Mohs surgical fee reimbursement, they kept the patients in-office, allowed the SkinCure radiation therapy technician to treat them with the SRT machine, for which the co-conspirator dermatologists had paid nothing. Also, the dermatologist paid nothing for SkinCure's radiation therapy technician's salary or SkinCure's other services. So in the case of a Medicare reimbursement, which SkinCure estimated was about \$7300,⁸⁴ for SRT treatment for one simple lesion, the referring dermatologist made 40%, \$2920, which was almost twice the total reimbursement for the gold standard, Mohs Surgery treatment. Referring dermatologists received 0% of the Moh's surgeon's reimbursement from Medicare. SkinCure pocketed the remainder of the Medicare reimbursement or about \$4400. Even the Mohs surgeons almost doubled their Medicare reimbursement by choosing SRT treatment over Mohs Surgery—\$2920 versus \$1500.

118. The SkinCure contracts with the dermatologists created an unlawful financial interest for the co-conspirator dermatologist in SkinCure. This violated *Stark*.⁸⁵ Such interest arose because SkinCure, among other things, (1) billed and collected from Medicare, in the name of the dermatologist, for the SRT services performed in the dermatologist's office; (2) received the reimbursement for such treatments from Medicare; (3) deposited such reimbursements received from Medicare into a bank account in the name of the dermatologist but with SkinCure having complete dominion and control over the reimbursement funds received, including exclusive signatory control over the bank account; and, (4) then divided the reimbursement fee paid, by Medicare, by paying the dermatologist 40% of the reimbursement and SkinCure keeping 60%.

84 See Exhibit F, SkinCure Medicare Reimbursement Summary Table for treatment of a single lesion with the Sensus SRT-100-Vision machine.

85 42 U.S.C. § 1395nn.

119. The contracts between SkinCure and the dermatologist created an unlawful joint venture, which violated *Stark* and AKS just as the 2003 OIG Special Advisory Bulletin had warned. SkinCure paid bribes and kickbacks to co-conspirator as previously stated.

5. **SkinCure's Revenue From SRT Machine Lease And Other Services It Provided, Grossly Exceeded Fair Market Value - Basis For Fair Market Value**

120. SkinCure was paid more than fair market value for the services it provided. SkinCure was paid more than fair market value for the purported lease of the SRT-100-Vision machine it furnished the dermatologist. For example, Sensus'—the SRT machine manufacturer's—own public documents specifically state that a monthly rental payment for the SRT-100-Vision machine would be \$6000 per month.⁸⁶ That same document also states that each patient on average presents with 1.25 lesions for treatment. We can only assume that the manufacturer of the machine, Sensus, knows what constitutes a fair market value, rental price for the machine. SkinCure advertises that it pays its radiation therapy technicians \$35.00 per hour, which translates to about \$5600 per month. We assume that is fair market value. It pays its billing and collection employees \$12-\$19 per hour but they are working at the SkinCure home office working with all of SkinCure's co-conspirator dermatologists, and devoting small amounts of time every month to each one. The same could be said for the Medical Physicist, the account manager and the person who handled the one-time State radiation registrations and filings.

121. A reasonable estimate for SkinCure's monthly expenses for each SRT machine placed in a co-conspirator dermatologist's office would be no more than \$15,000. At \$7300 per lesion and

⁸⁶ See Exhibit D, "The Sensus Healthcare Multi-Scenario NMSC Vision SRT-100 Reimbursement Table."

five patients per month and six lesions per month, the minimum Medicare reimbursement each month for a single SRT machine is \$43,800. 60% of that figure—the SkinCure fee split—is \$25,980. So even with a SRT machine seeing the minimum number of patients, SkinCure realized nearly an \$11,000 per month profit. But Relator has firsthand knowledge of at least one dermatologist in Tennessee, defendant, Dr. Meredith Overholt, at The Skin Wellness Center in Knoxville, Tennessee, who told Relator that, for at least the past year SkinCure has been treating 25-30 patients per month at her clinic with SkinCure’s SRT-100-Vision machine. At 30 patients per month and 1.25 lesions per patient, with Medicare paying for 70% of the patients treated, that is nearly \$200,000 per month or \$2.4 Million Dollars annual reimbursement from Medicare alone for that one practice with one SRT-100-Vision machine. SkinCure’s 60% fee split from that practice would be about \$120,000 per month or about \$1,450,000 per year, far in excess of the fair market value rental for the machine and the fair market costs of the other services and items SkinCure provided its co-conspirator dermatologists.

122. Relator has firsthand knowledge that SkinCure has placed SRT machines at the following dermatology offices in Tennessee: Pinnacle’s Murfreesboro Dermatology and Belle Meade Dermatology; and The Skin Wellness Center in Knoxville. He was personally told by defendant, Brandt, on November 8, 2017, in Brentwood that SkinCure had placed SRT machines in Branson, Missouri, Stow, Ohio and throughout Florida. At the American Academy of Dermatology meeting in Washington, D. C., in March 2019, Brandt--in an outburst of braggadocio--personally confirmed to Relator that SkinCure had additionally placed SRT machines in Los Angeles, California, Atlanta, Charlotte, Durham, Savannah, Minneapolis, New York City, New Jersey, Connecticut, Illinois, Michigan, among other places nationally using the SRT Turnkey Implementation Program.

123. SkinCure demanded that before it would place a SRT machine in a dermatologist’s

office, that dermatologist had to all but guarantee that at least five patients per month would be treated using the machine. Relator has first hand knowledge of this demand from his discussion with Brandt and his employment with Pinnacle and the decision to place a SkinCure provided SRT-100-Vision machine at Pinnacle's Belle Meade clinic. This demand itself was a violation of the public policy against over utilization that resulted in Congress passing *Stark I*, *Stark II* and AKS. In the contract language of the SRT Turnkey Implementation Program, SkinCure retained the right to remove its SRT-100-Vision machine from a co-conspirator dermatologist's clinic if certain minimum threshold numbers of patients treated every month was not met. The defendant conspirators' compliance with the demand resulted in their multiple and on-going violations of *Stark* and AKS.

6. Private Equity Investors Mastermind The Pinnacle Fraud And Conspiracy

124. Private equity investors in Pinnacle, defendants, Chicago Pacific Founders Tolan, Hatcher, Varnier and Bonner, exercised operational dominion and control over the business activities of Pinnacle from about March 2017, when they began investing in the company, until the present. That controlling interest is best demonstrated by the fact that Pinnacle has a seven person voting Board of Directors, with defendants, Tolan, Hatcher, Varnier and Bonner, filling four of those positions. The four had controlling votes on the board. They each were partners or affiliates of the private equity firm, Chicago Pacific Founder. By their favorable votes, along with the favorable votes of defendants, Eckes, Rios and Lapinski, they each approved, authorized and instigated Pinnacle's contract with SkinCure, to sign up for the SRT Turnkey Implementation Program, which became effective in September 2019, when Pinnacle joined the fraudulent conspiracy.

125. As a result of the Pinnacle contract, SkinCure placed and operated five SRT machines

at Pinnacle locations in Joliet, Hoffman Estates and Orland Park, Illinois, and at Murfreesboro and Belle Meade, Tennessee. They have plans to place another SRT at their Brighton, Michigan facility during 2020.

7. **Private Equity Investors Knowingly Financed And Fueled The Flames Of SkinCure's Nationwide Fraud And Conspiracy**

126. As discussed previously in the "Parties" section of this Verified Complaint, defendants, CapX Partners, Jeffrey S. Pfeffer, Fountain Partners d/b/a, Seacoast Capital, Tom Carter and John Van Hooser, (collectively "private equity finance defendant(s)"), either knew, should have known or recklessly disregarded the fact that the SkinCure business model was based on paying kickbacks and bribes to co-conspirator dermatologist defendants in exchange for referrals of their patients to SkinCure for or to provide DHS to those patients in the form of superficial radiation therapy services using a SkinCure owned SRT-100-Vision radiation machine, operated by a SkinCure employed, board certified, radiation therapy technician, with such services performed in the dermatologist defendant's clinic. SkinCure's bribes and kickbacks were an AKS violation. The co-conspirator dermatologists' referrals of Medicare patients to SkinCure were *Stark* violations. Each of these violations gave rise to a False Claims Act violation. The private equity finance defendants each knew, should have known or recklessly disregarded, SkinCure's violations of AKS, *Stark* and the False Claims Act. The moment the contracts were signed for the private equity finance defendants to loan money to SkinCure, said defendants became co-conspirators with SkinCure to defraud the United States and the States and the American taxpayer and to violate AKS, *Stark* and the False Claims Act.

D. Specific Examples Of Defendants' Fraud And Conspiracy, About Which Relator Has First Hand Knowledge

127. Relator has firsthand knowledge of three separate instances of the operation and details of defendants' fraudulent scheme and conspiracy. The first occurred in November 2017, while he was Chief Executive Officer of Tennessee Dermatology, and defendant, Kerwin Brandt, presented an early version of the fraudulent scheme to Brentwood Dermatology, a Tennessee Dermatology affiliate, located in Brentwood, Tennessee. The second occurred in June and July 2019, Relator met on two occasions with Dr. Meredith Overholt, the owner of The Skin Wellness Center in Knoxville, Tennessee. She had contracted with SkinCure signing on to its SRT Turnkey Implementation Program and told relator about her experience with the scheme and the financial windfall her practice had received since SkinCure installed its SRT machine in her office practice location. The third occurred from August 2019 until March 13, 2020, while relator was employed by defendant, Pinnacle, and is based on personal observations and conversations with Pinnacle CEO, and defendant, Chad Eckes. Since March 2017, when he first met Stephanie Owen, Regional Sales Manager for the SRT machine manufacturer, Sensus Healthcare, and its Nashville based account executive, Amanda Redden, in Memphis at a meeting of the Tennessee Dermatology Association held at Bass Pro Shops on Mud Island at the Pyramid, Relator gleaned much additional information about the SkinCure fraud scheme, and its national scope, directly from them.

1. SkinCure and Kerwin Brandt's Fraudulent Proposal To Brentwood Dermatology On November 8, 2017

(a) A Little Background

128. In October 2017, The Tennessee Dermatology Association meeting was held at Bass Pro Shops at the Pyramid on Mud Island in Memphis, Tennessee. While at the meeting, Relator met two sales representatives for Sensus Healthcare – Sensus manufactured the SRT-100-Vision superficial radiation machine -- Stephanie Owen, Regional Sale Manager, from Florida and Amanda Redden, Account Executive from Nashville. The discussion began with Relator explaining his experience with brachytherapy, another radiation therapy treatment for non-melanoma skin cancer and how Medicare reimbursement for the procedure went from \$40,000 per lesion to \$180 once Medicare adjusted the code for the superficial application of radiation. Since Relator was CEO of Tennessee Dermatology, the largest association of dermatologists in Tennessee, Stephanie and Amanda were trying to sell SRT machines through Relator to the group.⁸⁷

129. At one point during the discussion Stephanie said “if capital outlay is a concern of yours, we have a partner company called SkinCure where they outlay all of the capital it is a turnkey agreement where SkinCure does everything for you . . . the only downside is that they keep a percentage of the collections, but you will get our premium device . . . the SRT-100-Vision. With it, you will be able to bill for a higher amount. Creger then asked Stephanie, “So if I understand this, SkinCure will provide everything, we just need to refer the patients and share in the revenue?” She affirmed Creger’s understanding. Creger then asked her where SkinCure had this program up and running and was told by Stephanie, “in Branson, Missouri, Cleveland, Ohio and several places in Florida.

87 See Exhibit G, Relator, Dan Creger’s Summary Timeline.

(b) The Stunning Admissions Against Interest By Brandt On November 8, 2017, In Brentwood, Tennessee

130. On November 8, 2017, defendant, Kerwin Brandt, CEO of SkinCure met in Brentwood over dinner with Relator and Dr. John Q. Binhlam of Brentwood Dermatology, an affiliate of Tennessee Dermatology. The purpose of the meeting was for Brandt to present the SkinCure SRT Turnkey Implementation Program and about placing a SRT-100-Vision superficial radiation machine at Brentwood Dermatology. Brandt told Relator during the meeting that through the program, SkinCure would: (1) buy the SRT-100-Vision machine and place it in our office at no charge; (2) SkinCure would also, at no charge, employ and place a board certified radiation therapy technician in our office to operate the SRT machine, (he underscored that a SkinCure employee, not a dermatology practice employee, would deploy and operate the SRT machine); (3) at all times SkinCure retained ownership of the SRT machine and "if it is not producing a specified amount, then we will remove it at our discretion;" (4) "because SkinCure is funding the \$495,000 cost for the SRT machine and the additional costs to get it up and running, SkinCure will take 60% of any reimbursement and you keep 40%;" (5) bill for treatment using the SRT machine, as a purported agent for the practice, under the practice's Tax ID Number and in the case of Medicare/Medicaid patients its CMS Provider/Supplier Billing Number; (6) receive Medicare reimbursements into a bank account controlled by SkinCure, from which account SkinCure would pay the co-conspirator dermatologists their 40% cut.

131. After Brandt's initial explanation, Relator looked at him in disbelief. He replied,

"Yeah, I know, nobody has a business model like this" Creger then asked, "Who else is doing this with you?" Brandt responded, " We have devices and agreements in Branson, Missouri, just outside Cleveland in Stow, Ohio and all over Florida. We could have 50 SRT units in place in dermatology offices by the end of the year." Creger responded, "Seriously, that's nearly \$25,000,000 in capital outlay, you must have a deep pocket or own a bank." Brandt then said, "Funding is not an issue for us. . . . We keep 60% and the physician gets 40%. That is more than a fair business arrangement with no [financial] risk for the practice and we are funding all the expenses. We are taking all of the financial risks, and you are getting the referral income. I'll send you the agreement that all the practices have signed, tomorrow morning so you can look it over. The next morning, November 9, 2017, Brandt did E-Mail the proposed contract documents for Brentwood Dermatology to the Relator."⁸⁸

132. The foregoing admissions against interest—admissions of SkinCure's violations of Stark and the Anti-Kickback Statute—by defendant Kerwin Brandt, the highest ranking executive officer of defendant, SkinCure, together with their documentary confirmation through the proposed contract documents sent to Relator on November 9, 2017, can only be described as stunning.

133. During a conversation Relator had with Brandt in December 2017, he told Brandt that Brentwood Dermatology was not going to sign up with the SkinCure, SRT Turnkey Implementation Program and was not going to put a SkinCure SRT machine into its clinic.

Relator told Brandt that he was not comfortable with the SkinCure program.

⁸⁸ See Exhibit H, SkinCure's proposed contract documents sent to Relator by CEO, Brandt, on November 9, 2017.

Creger told him, No thanks, we [Tennessee Dermatology] are going to pass. No hard feelings.⁸⁹

(c) Admissions Against Interest Made By Brandt To Relator On Other Occasions

134. In March 2019 at the American Academy of Dermatology meeting in Washington, D.C., Relator talked with Brandt and said to him, "I understand you have placed [SRT] machines in Atlanta, Savannah, Durham, Charlotte, with Demitri in Louisiana, Tareen in Minneapolis, New York City, New Jersey and all over Florida." In reply Brandt said, "and in Connecticut, Ohio, Illinois and Michigan . . . how did you hear about all of those?" Relator replied, "I'm well known and I know a lot of people. 2018 was a good year for you. . . . Have you changed your fee from the 60/40 split?" In a condescending tone, Brandt stated, "We have so much business coming in we don't need to lower our agreement If the practice does not want to do it, then they just don't sign it." *From March 2019, Brandt avoided Relator at professional meetings that they both attended.*

2. SkinCure Fraud At The Skin Wellness Center, Knoxville, Tennessee

(a) Relator Made Two Visits To The Skin Wellness Center: June 30, 2019, And July 17, 2019

135. On June 28, 2019, in his capacity as CEO of Tennessee Dermatology, Relator made a cold call on The Skin Wellness Center in Knoxville and met with its owner, dermatologist, Dr. Meredith Overholt. (Relator had first met Dr. Overholt at the American Academy of Dermatology

⁸⁹ See Exhibit I, Relator's Factual Timeline

meeting in Washington, D.C. in March 2019.) She welcomed Relator and showed him around the office and specifically showed him the SRT machine that SkinCure had installed in her office. Relator told Dr. Overholt, "You are doing much better than our clinics to shell out \$500,000 for an SRT machine."

136. Dr. Overholt then introduced Relator to the radiation therapy technician who operated the SkinCure SRT machine. She was wearing a lab shirt with the SkinCure logo and the words "SkinCure" embossed over the breast pocket. Relator then turned to Dr. Overholt and said, "You didn't buy the SRT machine after all, you did that agreement with Kerwin? To which Dr. Overholt replied, "You know Kerwin? It's an amazing thing they do for you. I have no money laid out, and I get 40% of the revenue . . . We had to give up this room that used to be an employee coat room. SkinCure handles the billings, and collections . . . they even provide the radiation technologist. I guess that's why they have over 100 places that have signed their agreement. It seems like a no-brainer."

137. Relator had a brief conversation with the technician where he asked, "So let me get this straight, you are an employee of SkinCure; not The Skin Wellness Center, is that right?" The technician replied, "That's correct. I work for SkinCure, but I'm located here and work at the Wellness Center."

138. Then, on July 17, 2019, Relator was back in Knoxville and took Dr. Overholt and her medical partner, Dr. Kimberly Grande, and office manager to dinner at Chesapeake's Restaurant in Knoxville. Over dinner, the three women affirmed to Relator that, "What SkinCure does is a no-brainer. Pretty slick, we refer patients and we get paid. It has substantially helped our financial picture. It almost seems too good to be true. No issues for us so far . . . works seamlessly" In other

discussions with Dr. Overholt, she told Relator that the Skin Wellness Center expected to realize about \$1,000,000 annually from their 40% reimbursement from use of the single SkinCure SRT machine in their office. The Skin Wellness Center just referred its Medicare patients to SkinCure for superficial radiation therapy services, SkinCure prepared invoices for such services, presented the invoices to Medicare for payment and then paid The Skin Wellness Center its 40% of the Medicare reimbursement. And yes, it would be a no-brainer if it were not illegal—a violation of *Stark* and the Anti-Kickback Statute.

(b) Admissions Against Interest By Dr. Overholt And The SkinCure Radiation Therapy Technician

139. During his two visits with Dr. Overholt and the SkinCure radiation therapy technician, several significant admissions against interest were made to Relator, including, By Dr. Overholt:

- (a) She and The SkinWellnessCenter had contracted with SkinCure using its SRT Turnkey Implementation Program;
- (b) SkinCure had provided her and The Skin Wellness Center, at no charge, with the following:
 - (i) a \$495,000 SRT-100-Vision superficial radiation therapy machine;
 - (ii) a board certified, radiation therapy technician;
 - (iii) a lead lined treatment space;
 - (iv) registration and filing services with the State of Tennessee;
 - (v) billing and collection services for treatment of all patients receiving the SkinCure SRT machine, radiation therapy treatments including Medicare billings;
- (c) She confirmed that The Skin Wellness Center received 40% of all

reimbursements, which SkinCure received for treatment of her patients using the SRT machine, including 40% of all Medicare reimbursements;

- (d) She further confirmed that she no longer refers her patients out-of-office to a Mohs surgeon;
- (e) SkinCure treats 25-30 patients per month at The Skin Wellness Center using the SkinCure SRT machine, operated by the SkinCure radiation therapy technician;
- (f) Dr. Overholt said that revenues at The Skin Wellness Center had increased about \$1,000,000 in the last year from referrals of her patients to SkinCure for SRT superficial radiation therapy.

By The SkinCure, Radiation Therapy Technician:

- (a) She was wearing a lab shirt bearing the SkinCure Logo and the name "SkinCure" over the breast pocket;
- (b) She confirmed that she was not an employee of The Skin Wellness Center but was employed by SkinCure.

(c) Reasonable Inferences

140. From these admissions, reasonable inferences follow:

- (a) Dr. Overholt and The Skin Wellness Center received massive bribes and kickbacks from SkinCure, which violated AKS;
- (b) Such bribes and kickbacks gave Dr. Overholt and The Skin Wellness Center a financial interest in SkinCure;
- (c) Because of her financial interest, Dr. Overholt's referral of her patients to SkinCure for SRT superficial radiation treatment violated *Stark*;
- (d) SkinCure, not The Skin Wellness Center, owned the SRT-100-Vision machine and was providing DHS, superficial radiation therapy treatment for patients at The Skin Wellness Center;
- (e) SkinCure's radiation therapy technician, not Dr. Meredith Overholt, was the "Radiation Safety Officer or Person in charge of X-ray

equipment” at The Skin Wellness Center;

(f) For personal, financial gain, Dr. Overholt referred her patients to SkinCure for SRT treatment and virtually stopped referring any patient out-of-office for Mohs surgery—still the Gold Standard—for treating more complex non-melanoma skin cancers;

(g) The SkinCure SRT Turnkey Implementation Program encourages, and in the case of Dr. Overholt and The Skin Wellness Center, actually caused, over utilization of SRT superficial radiation therapy, for financial gain.

(h) Dr. Overholt, Dr. Grande and The Skin Wellness Center were complicit with SkinCure in preparing false “Registration of X-ray Producing Equipment” documentation for the State of Tennessee. Such documentation falsely represented that The Skin Wellness Center owned “Sensus SN:1812-2104” superficial radiation machine. Such documentation falsely represented that “Meredith Overholt” was the “Radiation Safety Officer or person in charge of x-ray equipment.” These were false statements. SkinCure at all material times owned said SRT machine and its radiation technician placed at The Skin Wellness Center by SkinCure was the “Radiation Safety Officer or person in charge of x-ray equipment.”

3. **The SkinCure Fraudulent Program At Pinnacle’s Murfreesboro Dermatology Clinic, September 2019- March 13, 2020**

141. In July 2019, Relator interviewed, in Nashville, face-to-face with defendant, Eckes, to become the Chief Growth Officer at defendant, Pinnacle. At the end of this meeting, Eckes asked Relator about implementing radiation therapy into a clinic for treatment of non-melanoma skin cancers. *Eckes further asked Relator if he had heard of the SkinCure business model. Relator told Eckes that he had met Brandt but that he was not a fan of the SkinCure program or business model. For that reason, Tennessee Dermatology decided to purchase a smaller SRT machine for Dr. Loven.*

142. In reply, Eckes said, "I like SkinCure, there is no financial risk for us, it is all upside and they take care of everything. We already have a couple of SkinCure agreements in place and Murfreesboro will be the first one in Tennessee." Relator told Eckes, "You should do it the legitimate way and buy the machine like any other service line you provide to patients." Eckes replied, "I'd rather use our capital for other purposes . . . especially when Kerwin is willing to use his capital. This is a no-brainer for me" Relator replied that, "If you hire me, you will have someone on your team who has done the whole soup to nuts roll out of SRT into a clinic, without using the SkinCure model. Do it the right way in the first place." Eckes concluded the discussion on SkinCure and its SRT program by saying, "I'd have to look at our agreement (with SkinCure) if we can even do that, you know add a SRT machine without them involved."

143. Relator's July 2019 colloquy with Eckes was a precursor to covered, protected conduct with him later, on multiple occasions, that resulted in his retaliatory discharge.

144. Relator was hired as Pinnacle's Chief Growth Officer and began work on September 3, 2019, the same day Pinnacle purchased Murfreesboro Dermatology. On September 16, 2019, Pinnacle purchased Belle Meade Dermatology. Dr. Jay Smith, a dermatologist, Mohs surgeon working at both Tennessee locations, informed Relator that the decision had been made to bring the SkinCure program and SRT machine to Murfreesboro. During a September 2019 conversation with Relator, Dr. Smith stated that, "SkinCure does it all, they pay for the expensive SRT machine with all the bells and whistles, they pay for all the construction remodel (the lead-lined room) and they bring their own radiation therapy technician. All I need to do is refer the patients to them, and they

provide the radiation therapy, they bill for the service and collect the Medicare reimbursement, then everybody splits the money.

145. Eckes told Relator in either September or October of 2019, that he had “pulled the trigger for the SkinCure agreement for Murfreesboro. We should be up and going by November 2019.” On that occasion Relator told Eckes, “you know my thoughts on SkinCure. . . .” Eckes then said, “I hope its above board because we are putting one in Minneapolis and one in Belle Meade. I have commitments on hitting certain EBITDA numbers and SkinCure . . . [is] a big part of hitting those numbers I have committed to hitting with the board. It’s a big nut to hit, so we have to execute on the plans I submitted to the board.” The CEO of Pinnacle was far more interested in hitting his financial numbers to please the private equity investors, controlling the Pinnacle Board than obeying the law or caring for Pinnacle’s patients.

146. Dr. Jay Smith, told Relator that he had expressed his concerns to Pinnacle’s, Regional Vice President, Barbara Dominic, that he did not think there were enough patients at Belle Meade to justify adding a SkinCure SRT machine. Dominic’s reply was, “Well Chad [Eckes] says otherwise and one is going in there.” The point being that Pinnacle profits overruled medical best judgment.

147. As Chief Growth Officer for Pinnacle, officed in Nashville, Relator had firsthand knowledge of the preparation, installation and operation of the SkinCure SRT machine at the Murfreesboro clinic. SkinCure did the following at Murfreesboro: (1) purchased and paid for a SRT-100-Vision, superficial radiation therapy machine at no charge to Pinnacle; (2) designed and paid for lead-lining a room where the SRT machine would operate at no cost to Pinnacle; (3) solicited, interviewed, and hired a radiation therapy technician, paid her salary, provided her benefits, paid her

with holdings and placed her at the Murfreesboro clinic at no cost to Pinnacle; (4) prepared and filed all registrations and filings for the SRT machine installed at the Murfreesboro clinic at no charge to Pinnacle; (5) billed Medicare/Medicaid for SRT services under Pinnacle's name and its tax and Medicare provider/supplier billing numbers and collected same at no charge to Pinnacle; (6) paid Pinnacle its 40% share of reimbursement, including reimbursements from Medicare.

148. The SkinCure radiation therapy technician was Kathleen Robertson. She was interviewed, selected and hired by SkinCure without input from Pinnacle. One day, she just showed up at Pinnacle's Murfreesboro clinic. She wore a lab shirt with the SkinCure logo on it and the name SkinCure under the Logo. She was the only person who operated the SkinCure SRT machine from the time it was installed and operational in November 2019, until Relator's employment with Pinnacle ended on March 13, 2020. She exercised complete dominion and control over the SkinCure SRT machine, its function and operation, providing therapy to Pinnacle's non-melanoma skin cancer patients who received SRT treatment during that time at the Murfreesboro clinic. Ms. Robertson was the Radiation Safety Officer or person in charge of x-ray equipment at Pinnacle's Murfreesboro clinic beginning in November 2019, when the SRT machine was installed by SkinCure.

149. SkinCure's procedure and preparation of fraudulent bills for SRT radiation treatment provided at Pinnacle's Murfreesboro clinic, for submission to Medicare were the following:

- (1) The patient was seen by a Murfreesboro clinic dermatologist;
- (2) The treating dermatologist decided if the patient's skin cancer would be treated with the SRT machine and would mark the area of the body to be treated;
- (3) The dermatologist would then have the patient taken to the SkinCure, radiation therapy technician, Kathleen Robertson, for SRT treatment;

- (4) Using the SkinCure owned, SRT machine, Ms. Robertson would make machine settings, determine time of treatment and select particular machine appurtenances to administer superficial radiation therapy to the area of the body marked by the dermatologist;
- (5) Once the SRT treatment was completed, Ms. Robertson then accessed the Murfreesboro Dermatology Electronic Medical Access billing software, ("EMA"), and entered into the patient's chart, the CPT codes for the treatment services she had just provided the patient;
- (6) Later that day or perhaps the next day SkinCure billing personnel from its Burr Ridge, Illinois home office accessed the patient's chart at Murfreesboro Dermatology, through EMA, to obtain billing information for a particular patient;
- (7) The Burr Ridge billing personnel then prepared a bill for submission to Medicare or a private third party healthcare program for payment;
- (8) The Burr Ridge billing person then submitted the completed bill to Medicare for payment; and,
- (9) The Medicare reimbursement was sent to a SkinCure controlled bank account from which it paid Pinnacle its 40% cut.

The bills submitted by SkinCure's Burr Ridge billing personnel to Medicare, et al. for payment for Murfreesboro Dermatology patients, were fraudulent bills, because the medical services being billed for were obtained due to kickbacks paid by SkinCure to Murfreesboro Dermatology in exchange for its unlawful referral of patients to SkinCure.

4. Material Information Relator Gleaned From Sensus Account Executive, Amanda Redden

150. Amanda Redden, Account Executive, with Sensus Healthcare, stationed in Nashville, continued to call on Relator over the next two years until she left the employ of Sensus in about September 2019. She was trying to sell SRT machines to the dermatology practices of Tennessee

Dermatology. During his encounters with Redden, she told Relator about selling the more expensive SRT-100-Vision machine in states other than Tennessee. Relator asked her, "How are you able to hit your numbers?" Redden told Relator, "SkinCure is behind it . . . with their turnkey, no financial risk to the dermatologist, program. Redden told Relator that Sensus had placed SRT machines through SkinCure in Los Angeles, California, at Demitri Dermatology in Louisiana, at multiple locations with Piedmont Plastic Surgery and Dermatology throughout North Carolina, a practice in Jackson, Tennessee, Dermatology Specialists in Huntsville, Alabama, practices in Durham, and Charlotte, North Carolina, and two practices in Greenville, South Carolina.

5. Medicare Paid Reimbursements, Only Because It Was Unaware of Defendants' Fraud

151. Medicare, not knowing of defendants' conspiracy or of the violations of *Stark* and AKS or the false and fraudulent invoices, willfully submitted by SkinCure for payment, paid such false and fraudulent invoices, and has done so since 2016 and continues through the present time, unwittingly, to pay. Had the Government known about such violations of law and such false and fraudulent invoices, it would not have paid defendants one dime.

E. Defendants' Elaborate Cover Up Of Their Fraud And Conspiracy

1. The Very Name "SkinCure Oncology" Is A Fraud

152. The defendant conspirators' cover up of their fraud began at the conception of SkinCure, when they selected its deceptive name, SkinCure Oncology. SkinCure does not provide medical oncology services. Relator suspects that SkinCure does not have in its full time employ even one single person who is a trained, licensed, medical oncologist or radiation oncologist. SkinCure

is a sales organization marketing superficial radiation therapy services, and selling them by paying bribes and kickbacks in exchange for unlawful Medicare patient referrals from its co-conspirator dermatologists, through its fraudulent SRT Turnkey Implementation Program.

153. So why would SkinCure represent itself to be an oncology service provider, when it is not? The simple answer is to hide and mislead the Federal Government and the States from what it really is doing. The word oncology according to the American Heritage Dictionary is the “scientific study of tumors.” SkinCure is not engaged in the scientific study of tumors; they are unlawfully paying kickbacks to co-conspirator dermatologists to sell their “SRT Turnkey Implementation Program.” They are unlawfully providing DHS in the form of radiation therapy services, which they are not approved by Medicare to provide and for which they cannot bill Federal or State healthcare programs in the name of SkinCure.

154. The only thing SkinCure is studying is how to increase the market for their fraudulent program so they can present more and more false bills to Medicare and other Federal and State healthcare programs, for payment, to receive more and more unlawful reimbursements at tax payers’ expense. And their deception continues.

2. SkinCure And Co-conspirator Dermatologists Misrepresent Ownership Of The SRT Machine

155. SkinCure and the co-conspirator, dermatologists misrepresent who actually owns the \$495,000, SRT machines that SkinCure provides its co-conspirator dermatologists at no charge. They execute registration and filing documents with the States to misrepresent and make it appear that the machines are owned by the co-conspirator dermatologists, not the true owner--SkinCure. Why would defendants do such a thing? There are three reasons. First, because SkinCure, not the co-conspirator

dermatologist, is providing the actual patient treatment using the SkinCure owned, SRT machine, operated by the SkinCure radiation therapy technician at the co-conspirator dermatologist's clinic. SkinCure cannot claim ownership because it cannot bill Medicare or any Federal or State healthcare program for such patient treatment. SkinCure is not, and has not been at any material time, a qualified Medicare Provider/Supplier. SkinCure does not have, and never has had, a Medicare Billing Number. In short, SkinCure cannot bill Medicare for any item or service in its own name. SkinCure dare not claim ownership of the \$495,000, SRT-100-Vision machines, because it would then clearly owe the State of Illinois 9% sales tax and annual use taxes on each of the approximately 200 such machines purchased since October 2016. SkinCure's legitimate tax debt to the State of Illinois is \$15,000,000 or more. So it misrepresents true ownership of the SRT machines to continue to defraud Medicare and to avoid paying the State of Illinois at least \$15,000,000 in taxes..

156. Second, if SkinCure tries to claim that it is a *bona fide* leasor⁹⁰ of the SRT machine to its co-conspirator dermatologist it would forfeit any argument to claim entitlement to an exemption or "Safe Harbor" under *Stark*, if the Government discovers it to be operating equipment it has purportedly leased to its co-conspirator dermatologists.⁹¹

157. Third, to promote the cover up, it was essential that the co-conspirator dermatologist appear to own and operate the SRT machine and then bill Medicare for the treatment services performed using it. This provided the added cover up benefit that the false billings to Medicare were

90 SkinCure is not a bona fide leasor of the SRT machine because it has no discrete lease amount term in its SRT Turnkey Implementation Program with co-conspirator dermatologists. SkinCure give free access to the patients of its co-conspirator dermatologists.

91 42 C.F.R. § 411.357(b)(2).

spread out among many different healthcare providers, for lesser amounts, thus not raising red flags or attracting as much attention as would be attracted if SkinCure sent Medicare one huge bill. SkinCure and its co-conspirator dermatologists chose for Medicare and the American tax payer, “death by a thousand cuts” rather than one fatal blow. One fatal blow would have blown defendants’ cover.

3. **SkinCure And Co-conspirator Dermatologists Filed False Or Misleading SRT Machine Registration Documents, Some Under Oath, With The States**

158. Every State requires that radiological equipment employed for medical purposes be registered with a designated State agency. The public policy behind this requirement is to protect public health from the unauthorized or inappropriate use of radiation equipment. Under its SRT Turnkey Implementation Program, SkinCure took responsibility to register its SRT machine with the State authorities where its SRT machine was located. But SkinCure violated State law, in two material ways when it falsely registered the SkinCure owned SRT machines First, SkinCure misrepresented that the co-conspirator dermatologist, owned the \$495,000 SRT machine, which SkinCure had purchased and, therefore, owned. Second, SkinCure falsely stated that a co-conspirator dermatologist employee controlled or operated the SkinCure owned SRT machine. In truth, the SkinCure employed radiation therapy technician operated and exercised complete dominion and control over the SkinCure SRT machine. The co-conspirator dermatologists were each also complicit in the false registrations of SkinCure owned SRT machines. They allowed their names to be affixed to official State radiation machine registration documents that contained material false information and in some cases false information provided under oath on behalf of the co-conspirator dermatologists.

(a) SkinCure's False Documents to State of Georgia--Cole Dermatology

159. Relator knows of several examples of such false documents being filed by SkinCure on behalf of its co-conspirator dermatologists. For example, Relator has obtained from the State of Georgia Healthcare Facility Regulation Division a copy of two inspection reports completed on September 18 & 30, 2019, at defendant, Cole Dermatology & Aesthetics Center PC, 3525 Holcomb Bridge Road, Suite 100, Peachtree Corners, Georgia 30092.⁹² Each inspection report required the informant to provide the name of the entity, which was the "Provider or Supplier" of the X-ray services. On each form such entity was falsely identified as the defendant, Cole Dermatology & Aesthetics Center PC. It was not a provider or supplier of X-ray services using the SRT machine. No Cole Dermatology employee ever operated the SkinCure SRT machine placed at the Cole clinic. SkinCure provided, a board certified, radiation therapy technician to operate and maintain dominion and control over the SkinCure SRT machine.

160. Relator does not yet have a copy of the registration document filed, under oath, with the State of Georgia for the SkinCure SRT machine placed at the Cole Dermatology clinic. But given the false representation in the Cole Dermatology Inspection Report about who was the "Provider or Supplier" of radiation services, the reasonable inference is that SkinCure made the same misrepresentation on the SRT machine registration document. But SkinCure turned the misrepresentation about the SRT machine up a notch this time-- it was under oath. To the extent this information about Cole Dermatology clinic's SRT registration documents may be deemed publically

92 See Exhibit J, Two State of Georgia Inspection Reports Concerning Sensus SRT-100 Vision Superficial X-ray System.

disclosed information, Relator is the original source.

(b) **Dr. Lapinski's Misleading Statements To The State of Illinois**

161. Another example of a false or misleading registration document being filed occurred in the State of Illinois with defendant, Dr. Paula K. Lapinski. On September 13, 2019, Dr. Lapinski registered an SRT-100 Vision X-ray machine with the Illinois Emergency Management Agency.⁹³ Relator was employed by Pinnacle on the date of this registration and knows personally that neither Pinnacle nor Dr. Lapinski owned the machine being registered. The machine was owned by SkinCure. Yet nowhere on the registration document does SkinCure's name appear. At about the same time other similar false or misleading registration documents for SkinCure SRT machines were filed by two other Pinnacle doctors.⁹⁴ At least three other SkinCure co-conspirator non-Pinnacle doctors have filed similar false or misleading SRT machine registrations in Illinois for SkinCure SRT machines located at their clinics.⁹⁵ To the extent this information about these Illinois SRT registration documents may be deemed publically disclosed information, Relator is the original source.

(c) **SkinCure's False X-ray Machine Registration Document In Tennessee**

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- 93 See Exhibit K, Dr. Lapinski's registration on behalf of Pinnacle Dermatology of one SRT-100 Vision, X-ray machine.
- 94 See Exhibit L, Other false or misleading registration documents filed by Pinnacle doctors with the Illinois Emergency Management Agency.
- 95 See Exhibit M, Other false or misleading registration documents filed by non-Pinnacle dc-defendant dermatologists with the Illinois Emergency Management Agency.

162. On about March 20, 2019, SkinCure submitted a false X-ray Equipment Registration document to the State of Tennessee, Department of Environment and Conservation, Division of Radiological Health on behalf of The Skin Wellness Center in Knoxville.⁹⁶ Such registration document was false in two material particulars. First, SkinCure falsely stated and certified the The SkinCure Wellness Center was the owner of the Sensus radiation machine being registered, bearing Serial No.: SN:1812-2104. The machine bearing that serial number was a SRT-100-Vision, superficial radiation therapy machine that Relator personally saw when he visited The Skin Wellness Center on June 30, 2019. Relator was told by Dr. Overholt that the machine was furnished to The Skin Wellness Center by SkinCure at no charge. But title and ownership of the machine at all material times remained with the entity that paid \$495,000 for it and retained the right to remove it from The Skin Wellness Center if it was not generating sufficient revenue— SkinCure.

163. Second, SkinCure falsely certified that Meredith Overholt was the “Radiation Safety Officer or Person in charge of X-ray equipment.” Under its SRT Turnkey Implementation Program, SkinCure was obligated to provide Dr. Overholt with a “radiation safety officer,” (See Exhibit H, Terms & Conditions § 1.4(a)). SkinCure conveniently, and with deliberate calculation, left off Overholt’s medical title, “Dr.” lest including it would raise any suspicions that a physician would condescend to function as a “Radiation Safety Officer or Person in charge of X-ray equipment,” when those functions are almost always fulfilled by

⁹⁶ See Exhibit N. State of Tennessee Registration of X-ray Equipment Document.

the person maintaining dominion and control over the X-ray equipment and actually operating it to provide radiation therapy for patients. SkinCure's statement that "Meredith Overholt" was the radiation safety officer on Exhibit N was false. SkinCure's statement that The Skin Wellness Center owned the SRT-100-Vision machine was false.

164. Such false statements on an official State of Tennessee X-ray Registration were part of its nationwide coverup. SkinCure was hiding from the Government, the States and Medicare who was actually providing DHS in the form of superficial radiation therapy services. For reasons previously stated, SkinCure could not bill Medicare for those services. But to falsely bill Medicare, SkinCure had to make it appear that their co-conspirator dermatologists owned and operated the SRT-100-Vision machine was the entity providing radiation therapy for patients. Why did SkinCure create such a subterfuge? They did so for two reasons: (1) to falsely bill Medicare under their co-conspirator dermatologists' Medicare Provider/Suppliers' Billing Numbers and (2) to avoid paying the State of Illinois 9 % sales tax and annual use taxes on at least 200, SRT-100-Vision machines, purchase price, \$495,000 each. For their clandestine efforts, SkinCure and its co-conspirator dermatologists were handsomely rewarded. In Dr. Overholt's case, SkinCure took 60% of the Medicare reimbursement for devising and executing the fraudulent scheme; Dr. Overholt took 40% of the Medicare reimbursement for accepting bribes and kickbacks in exchange for referring her patients to SkinCure for SRT therapy treatments. All things considered, a tidy little fraud and conspiracy, but with just one problem, as the Frankie Vallee tune described, "... Just Too Good To Be True."

4. **SkinCure Became Each Co-Conspirator Dermatologist's Purported Agent To Register SRT Machines And To Bill Medicare And Other Federal And State Healthcare Programs**

165. Why would SkinCure demand in the terms of its SRT Turnkey

Implementation Program to be purported agent for each co-conspirator dermatologist for purposes of billing Medicare and registering SRT machines with the States? There is one simple reason: to maintain tight control over the fraud narrative. SkinCure had to make certain that it was the sole source of information to Medicare and the States concerning superficial radiation therapy services provided to Medicare beneficiaries and ownership of the SRT-100-Vision machines to ensure that its fraudulent story remained the same. SkinCure could not run the risk of allowing a co-conspirator dermatologist to slip up and mention to Medicare or the States that SkinCure was providing massive kickbacks in money and in kind or that SkinCure owned the SRT-100-Vision machine at the dermatology clinic and was the entity actually providing radiation services. SkinCure could not bill Medicare in its own name and it was not a legitimate Medicare billing agent for its co-conspirator dermatologists. SkinCure's Medicare billings on behalf of its co-conspirators were unlawful. At no material time, was SkinCure a legitimate Medicare billing agent. To pull off the deception—to defraud Medicare—SkinCure had to repeatedly make false statements about who owned the SRT-100-Vision machine, who provided radiation therapy services to Medicare beneficiaries; SkinCure's purported status as a Medicare billing agent for the dermatologists; and who was actually receiving the Medicare reimbursements—it was SkinCure—the co-conspirator dermatologists only received their 40% kickback. Critically, SkinCure also had to consistently deny and fraudulently

misrepresent its ownership of the SRT-100-Vision machines to avoid paying at least \$15,000,000 in sales and use taxes to the State of Illinois on about 200, \$495,000 SRT machines, which it has purchased.

166. SkinCure also had to completely control registration of its SRT-100-Vision radiation machines with the various States to complete its coverup. This was essential so that SkinCure could continue to make the following three material false representations to the States, that the co-conspirator dermatologists: (1) were owners of the SRT-100-Vision machines; (2) provided superficial radiation therapy services to Medicare beneficiaries; and, (3) were "Radiation Safety Officers or Persons in charge of x-ray equipment." Each of these representations were material and false. The first and third were made to hide from Medicare, and coverup the fact, that SkinCure had provided the SRT-100-Vision radiation machine to the co-conspirator as a bribe and kickback and also to hide SkinCure's ownership from Illinois taxing authorities. The second and third were made to hide from Medicare that SkinCure was providing Medicare beneficiaries with DHS, superficial radiation therapy, for which it was not an approved Medicare provider/supplier and for which it could not bill Medicare in its own name.

167. SkinCure could not risk allowing even one co-conspirator to bill Medicare, get into a dispute over a billing, get audited by Medicare and then "spoil the party" by revealing the unlawful kickbacks it received in cash and kind, in exchange for its own unlawful referrals or that SkinCure owned the SRT machine and was the unauthorized entity providing DHS—superficial radiation therapy treatment. For similar reasons, it could not allow a co-conspirator to handle the State registrations of the SRT-100-Vision machines, reveal in official State documents that SkinCure

owned the machine and was in complete command and control of its operation. SkinCure and the co-conspirator dermatologists made SkinCure billing Medicare and registering SRT machines essential and material terms of their contract and their cover up.

5. SkinCure And Co-Conspirator Dermatologists Made The Terms Of Their Business Arrangement Secret And Confidential

168. SkinCure and co-conspirator dermatologists made their business arrangement secret and confidential. Why would they do that? They did not want anyone, especially not the Government, to know about the terms of their arrangement which set forth the kickbacks SkinCure was paying its co-conspirator dermatologists in exchange for their unlawful referrals. But above all, they did not want anyone to know about, and particularly not the Government, the 40% kickbacks SkinCure was paying its co-conspirator dermatologist from every Medicare reimbursement and every reimbursement paid by any Federal or State healthcare programs.

VII. Truthfully Certifying Compliance With Stark And AKS Is A Condition Of Payment Under Federal Healthcare Laws, Including The False Claims Act

169. In a frequently cited, important decision,⁹⁷ this Court held that the defendants' continued participation in the Medicare program constituted an "implied certification that [they] will abide by and adhere to all statutes, rules and regulations governing that program."⁹⁸ Therefore, each time the defendants submitted a claim related to or derived from their knowing violations of these

⁹⁷ *United States ex rel. Pogue v. American Healthcorp., Inc.*, 914 F. Supp. 1507 (M.D. Tenn. 1996).

⁹⁸ *Id.* at 1509.

laws, they violated the implied certification of “continuing adherence to the requirements for participation in the program.”⁹⁹ In another important opinion, another district court held that, both the mere submission of claims for payment, statutorily prohibited by *Stark* and the submission of claims with false certification of compliance with AKS and *Stark* violate the False Claims Act.¹⁰⁰

170. In the certification section of every Medicare Enrollment Application every physician must certify, among other things that they “understand that payment of a claim is conditioned upon the claim and the underlying transaction complying with the Federal Anti-Kickback Statute . . . [and] . . . the *Stark* Law. . . . I will not knowingly order and/or certify as item and/or service . . . that allows a false or fraudulent claim to be presented for payment to Medicare.”¹⁰¹

171. By their knowing and willful presentment of false and fraudulent invoices to Medicare for payment, which defendants knew at the time of presentment to be false--defendants knew at presentment the invoices violated AKS and *Stark*-- and by their conspiracy to do so, defendants are guilty of a false, implied certification to Medicare. A truthful certification of compliance with AKS and *Stark*, is a condition of receiving reimbursement funds from Medicare.¹⁰²

172. By Defendants’ false certification to Medicare, they were not entitled to even present an invoice for payment to Medicare. Had Medicare been aware of their false certifications, at the time of invoice presentment, it would have paid them--not one dime.

99 *Id.*

100 *Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998).

101 Medicare Enrollment Application, CMS-8550 at Section 8.

102 *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2s 612, 614 (N.D. Ill. 2003), *aff’d* 517 F. 3d 449 (7th Cir. 2008).

173. Each defendant has willfully refused to repay the United States and the States the monies defendants have unlawfully received.¹⁰³

VIII. Damages To The Federal Government - Pro Forma Damage Estimates From 2016 To Present

174. SkinCure provided its co-conspirator dermatologists with CPT Code billing information as part of its marketing program for its fraudulent SRT Turnkey Implementation Program.¹⁰⁴ SkinCure did this to show the prospective dermatologist customer, or the already signed up co-conspirator dermatologist, the tremendous revenue stream of reimbursements possible from Medicare and other Federal and State healthcare programs. There were nine separate treatment activities, which could be billed to the Government and to the States for which Medicare would pay approved reimbursements totaling \$7,352.13 per lesion treated. For presentations of more extensive non-melanoma skin cancers, the reimbursement could be higher.

175. Brandt told Relator on November 8, 2017, that he had placed 46 SRT machines at that time and apparently that was the same number of machines that had been placed by January 11, 2018. In a press release on July 24, 2018, "SkinCure announces delivery [placement] of 69th SRT Vision Machine." This rate of placement averages out to one new SRT machine placed per week. So by January 1, 2019, the reasonable inference is that SkinCure had placed 100 SRT machines with co-

103 31 U.S.C. § 3729(a)(1)(C)&(G).

104 See Exhibit F, SkinCure Published, Medicare Approved, Reimbursements And CPT Codes for treatment activities performed in connection with the SkinCure SRT machine, by the SkinCure radiation therapy technician on co-conspirator, dermatologist's patients in such dermatologist's office.

conspirator dermatologists. At the same placement rate, during 2019, they would have placed 150 SRT machines by January 1, 2020. With just a bit of increased sales momentum—a reasonable inference--SkinCure will easily have placed 220 or more SRT machines with their co-conspirator, dermatology practices by January 1, 2021. The loan of \$30,000,000 from Seacoast on October 1, 2019, provided just such momentum. To the extent that any of this information is considered to be publically disclosed information, Relator is the original source.

176. Added to these facts and reasonable inferences, are the following additional reasonable inferences and assumptions: (1) each patient presents with on average 1.25 lesions;¹⁰⁵ (2) 70% of all patients treated by the SRT machine are 65 years old or older and, therefore, Medicare, Medicaid or other Government or State healthcare program beneficiaries;¹⁰⁶ (3) each SRT machine placed in a co-conspirator, dermatologist's office is treating at least 10 patients per month with superficial radiation therapy; (4) each of the 10 patients so treated are presenting on average with 1.25 lesions for treatment; (5) therefore, each SkinCure SRT machine placed is treating at least 12.5 lesions per month; (6) the lowest Medicare reimbursement per lesion is \$7,352.13/lesion X 12.5 lesions X 0.70 = equals an average Government healthcare monthly reimbursement of at least \$64,331.14 per SRT machine placed by SkinCure. Of that figure, SkinCure keeps \$38,598.68 and pays its co-conspirator, dermatologist a kick back of \$25,732.46 per month. Some of the SRT machines, like the one at The Wellness Center in Knoxville paid off much better, as we shall see.

177. But first, an analysis of fair market value is in order. Sensus own document stated that

105 See Exhibit D.

106 This will be Relator's sworn testimony at trial.

the monthly lease payment for a 60 month lease of an SRT-100-Vision machine should be \$6000/month.¹⁰⁷ The radiation therapy technicians were paid about \$35/hour. Even assuming a 40 hour week that comes to a monthly cost of about \$5600. Even generously assuming that the cost of the other monthly kickbacks provided by SkinCure to its co-conspirators averaged an additional \$5000/month, which they likely did not, SkinCure's profit on the transaction or the amount it received in payment for its purported lease of the SRT machine was ridiculously excessive. Its total monthly costs were about \$16,600 but its revenue from Government reimbursements was \$38,598.68 for a profit to SkinCure from only Government reimbursements of just at \$22,000/month on a machine treating only 10 patients per month.

178. The Skin Wellness Center profit figures are three times the average numbers just stated. Principal of the Center, Dr. Meredith Overholt, told Relator in June and July 2019, that they were treating as many as 30 patients per month using SkinCure's SRT machine. She also admitted that her referral of patients for Mohs surgery had almost completely dried up. Therefore, since the figures for Dr. Overholt's 30 patients are three times more than the figures for 10 patients. Her monthly kickback paid by SkinCure was about \$77,000. The monthly revenue realized by SkinCure on the Skin Wellness Center's single SRT machine was almost \$100,000. Subtracting the estimated monthly costs of \$16,600 for a single SRT machine turnkey program, gives SkinCure a monthly profit over \$80,000, a figure that is not fair market value for the equipment purportedly leased and services SkinCure provided—it is insanely excessive. And it is insanely excessive at the Government's and tax payer's expense.

107 See Exhibit D.

179. Based on evidence presented, the reasonable inference is that SkinCure's placement of SRT machines since 2016 has been approximately the following:

<u>Date</u>	<u>No. Of Machines Placed</u>
January 1, 2018	46
January 1, 2019	100
January 1, 2020	150
January 1, 2021	220

Assuming that 23 machines operated on average in 2017; 75 in 2018; 125 in 2019; and 185 in 2020 and that each machine treated 10 patients per month, likely a low average number and that those patients each presented with on average 1.25 lesions and that 70% of all patients were Medicare beneficiaries, the total damages to Medicare for the four year period are at least \$150,000,000 - \$200,000,000 and rapidly rising.

180. Relator has only been able to locate about 75, or about one-third, of the more than 200, SRT-100-Vision machines that SkinCure has fraudulently placed with co-conspirator dermatologists throughout the country. Where is the other two-thirds, and why are they not easily located? The simple answer is—coverup. Most co-conspirator dermatologists do not want their names or addresses associated with SkinCure and its illegal SRT Turnkey Implementation Program. They know it is wrong. They know it violates Federal and State law. But their greed prevailed. They signed up with SkinCure; they just do not want the Government to know they signed up. They want the revenues generated by the fraudulently placed SRT machines; they just do not want the SRT machines to be discovered by the Government at their clinics. These co-conspirator dermatologists do not allow their names or addresses to be published by SkinCure in its national advertising—another element of the

national coverup.

181. Undeterred, SkinCure has been busy since October 2019, putting its \$30,000,000 loan from Fountain Partners and Seacoast Capital to work, buying SRT-100-Vision machines and placing them with more and more new co-conspirator dermatologists to exponentially expand its fraud against Medicare.

CLAIMS FOR RELIEF

COUNT I

VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(A)

Presentment Of False or Fraudulent Claims, Statements, or Records

182. Relator re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

183. This is a civil action brought by Relator on behalf of the United States against Defendants under the Federal False Claims Act, 31 U.S.C. §§ 3729-3733.

184. Under the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended on May 20, 2009, Defendants have violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval.

185. Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to CMS or its agents, or other Government Health Care Programs.

186. Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.

187. Government Payors, unaware of these violations of the Federal FCA and the false or

fraudulent nature of the claims presented or caused to be presented, and in reliance on the accuracy of these claims, paid for purported medical products and services performed for patients insured by federally funded health insurance programs, including Medicare, Medicaid, and CHAMPUS/TRICARE. Had the United States known that the bills presented by Defendants, or that Defendants caused to be presented, were false or fraudulent, payment would not have been made for such claims.

188. Defendants' unlawful conduct occurred from on or around October 10, 2016, until the present and is continuing, and has caused the United States to suffer damages.

189. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under 31 U.S.C. § 3729(a)(1) and (3), together with statutory attorneys fees, interest and prejudgment interest.

COUNT II
VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(B)
Creation or Use of False Statements or Records Material To A False or Fraudulent Claim

190. Relator re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

191. This is a civil action brought by Relator on behalf of the United States against Defendants under the Federal False Claims Act, 31 U.S.C. §§ 3729-3733.

192. Under the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended on May 20, 2009, Defendants have violated 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim.

193. Defendants made, used, or caused to be made or used false or fraudulent records or

statements.

194. These false records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to CMS or its agents, or other Government Health Care Programs.

195. Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.

196. Government Payors, unaware of these violations of the Federal FCA and the false or fraudulent nature of the records or statements made, used, or caused to be made or used, and in reliance on the accuracy of these records or statements or the false or fraudulent claims to which these records or statements were material, paid for purported medical products or services performed for patients insured by federally funded health insurance programs, including Medicare, Medicaid, and CHAMPUS/TRICARE. Had the United States known that the bills presented by Defendants, or that Defendants caused to be presented, were false or fraudulent, payment would not have been made for such claims.

197. Defendants' unlawful conduct occurred from on or around October 10, 2016, until the present and is continuing, and has caused the United States to suffer damages.

198. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under 31 U.S.C. § 3729(a)(1)(B), together with statutory attorneys fees, interest and prejudgment interest.

COUNT III
VIOLATION OF THE FEDERAL FALSE CLAIMS ACT,
31 U.S.C. § 3729(a)(1)(G)
Knowingly Causing and Retaining Overpayments Received From the Government

199. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

200. This is a civil action brought by Relator on behalf of the United States against Defendants under the Federal False Claims Act, 31 U.S.C. §§ 3729-3733.

201. Under the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended on May 20, 2009, Defendants have violated 31 U.S.C. § 3729(a)(1)(G) by knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government. The term “obligation” means:

an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment. . . .

31 U.S.C. § 3729(b)(3).

202. Further, in the health care context, such as Medicaid, the term “obligation” is further defined as “[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment . . . is an obligation (as defined [in the Federal FCA]),” and an overpayment must be reported “[b]y the later of . . . 60 days after the date on which the overpayment was identified . . . or the date any corresponding cost report is due, if applicable.” Patient Protection and Affordable Care Act, Pub. L. 111-148, § 6402(d)(2), (3), 124 Stat. 119, 755 (codified at 42 U.S.C. § 1128J(d)).

203. Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above.

204. These false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to CMS or its agents, or other Government Health Care Programs.

205. Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.

206. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to CMS or its agents, or other Government Health Care Programs.

207. Defendants knew, or were deliberately ignorant or reckless in not knowing, that its conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to CMS or its agents, or other Government Health Care Programs.

208. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused its co-conspirator Defendants to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were tainted by violations of the *Stark* Law and Anti-Kickback Statute, and otherwise not properly reimbursable.

209. Defendants' knowing or intentional concealment or failure to report funds that were improperly received from Government Payors for services that were tainted by kickbacks and unlawful referrals and otherwise not properly reimbursable constitute unlawful avoidances or decreases of obligations to pay money owed to the United States.

210. Defendants' unlawful conduct occurred from on or around October 10, 2016, until the present and is continuing, and has caused the United States to suffer damages.

211. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under 31 U.S.C. § 3729(a)(1)(G), together with statutory attorneys fees, interest and prejudgment interest.

COUNT IV
VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(G)
Creating or Using False or Fraudulent Claims, Statements, and Records To
Avoid Refunding Monies To The Government

212. Relator re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

213. This is a civil action brought by Relator on behalf of the United States against Defendants under the Federal False Claims Act, 31 U.S.C. §§ 3729-3733.

214. Under the False Claims Act, 31 U.S.C. § 3729(a)(1), as amended on May 20, 2009, Defendants have violated 31 U.S.C. § 3729(a)(1)(C)&(G) by conspiring to (1) knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval; (2) make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim; (3) make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay, transmit or refund money or property to the government.

215. Defendants' conspiracy caused to be presented, false or fraudulent claims for payment or approval to CMS or its agents, or other Government Health Care Programs.

216. Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conspiracy to present false or fraudulent claims to CMS or its agents was unlawful.

217. Government Payors, unaware of defendants' conspiracy or of these violations of the

Federal FCA and the false or fraudulent nature of the claims presented or caused to be presented, and in reliance on the accuracy and purported truthfulness of these claims, paid for purported medical services performed for patients insured by federally funded health insurance programs, including Medicare, Medicaid, and CHAMPUS/TRICARE. Had the United States known that the bills presented by Defendants, or that Defendants caused to be presented through their conspiracy, were false or fraudulent, payment would not have been made for such claims.

218. Defendants' unlawful conduct and conspiracy occurred from on or around October 10, 2016, until the present and is continuing, and have caused the United States to suffer damages.

219. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under 31 U.S.C. § 3729(a)(1)(G).

COUNT V
VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(B)
Submission of Express and Implied False Certifications With Presentments of
False Invoices to The Government For Payment

220. Relator repeats and re-alleges the allegations and statements contained in all of the preceding paragraphs as though fully set forth herein.

221. In pertinent part, the False Claims Act establishes liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

222. Compliance with Stark and Anti-Kickback Laws were explicit conditions of payment under Federal Healthcare Programs. For each of the years 2016 to the present, Defendants certified compliance with the Federal Stark and Anti-Kickback Laws on their annual cost reports submitted to Federal Healthcare Programs. The Defendants' certifications of compliance with Federal Stark and

Anti-Kickback Laws were knowingly false. In reliance on the Defendants' express and implied certifications, the United States made payments to Defendants under Federal Healthcare Programs. If the United States had known that Defendants' certifications were false, Federal payments under the Federal Healthcare Programs would not have been made to Defendants for each of the years in question. Defendants' false records, false statements, and false certifications have caused the United States to suffer damages.

223. Defendants' unlawful conduct and conspiracy occurred from on or around October 10, 2016, until the present and is continuing, and have caused the United States to suffer damages.

224. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under 31 U.S.C. § 3729(a)(1)(G).

COUNT VI
VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(C)
Conspiring To Submit False Claims, or To Create or Use False Records or Statements
Material To a False Claim, or To Knowingly Retain Overpayments
From The United States, or Create and Use False Records To Avoid An
Obligation To Refund Monies To The United States or To Submit Express or Implied False
Certifications To The United States

225. Relator re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

226. The False Claims Act establishes liability for "any person who . . . conspires to commit a violation of subparagraph (A), (B), (D), (E), (F) of (G)."¹⁰⁸

227. Through the acts described above the defendants, and each of them, acting in concert with each other, conspired to submit false claims to the United States or to create or use false records

¹⁰⁸ 31 U.S.C. § 3729(a)(1)(C).

or statements material to a false claim or to knowingly retain overpayments from the United States or create or use false records to avoid an obligation to refund monies to the United States or to submit express or implied false certifications to the United States.

228. The defendants covered up and hid their conspiracy from the United States and at no material time did the United States have knowledge of defendants' said unlawful conduct.

229. As a result, the United States was unaware of the false claims submitted and caused by the defendants and the United States paid and continues to pay claims that would not have been paid if the defendants' unlawful conduct was known to the United States.

230. Defendants' unlawful conduct and conspiracy occurred from on or around October 10, 2016, until the present and is continuing, and have caused the United States to suffer damages.

231. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under 31 U.S.C. § 3729(a)(1)(C).

COUNT VII
Retaliation Against Relator in Violation of 31 U.S.C. § 3730(h)

232. Relator re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

233. In August 2019, during his employment interview, Relator began discussing his opinion about the impropriety of the SkinCure program with Pinnacle CEO, Chad Eckes, even before he was hired as Chief Growth Officer. Eckes told Relator that he was considering signing up for the SkinCure, SRT Turnkey Implementation Program. Relator specifically told Eckes that if he was hired as Chief Growth Officer, Eckes would have an employee

who was not a fan of the SkinCure program.

234. Relator was hired by Eckes as Chief Growth Officer for Pinnacle and his first day on the job was September 3, 2019. Later in September 2019, Relator had another conversation with Eckes about the SkinCure program with Relator expressing skepticism about the program. Relator told Eckes, "Let me handle the SRT therapy at the practices and let's not do the SkinCure program." Eckes stated that he did not know I that was possible due to the extent of the on-going negotiations with SkinCure.

235. Again, in either late October or early November 2019 at about the time the SkinCure owned SRT-100-Vision machine was installed and became operational at Pinnacle's Murfreesboro Dermatology Practice, Relator in face-to-face meetings with Eckes in Nashville, expressed skepticism about the propriety of the SkinCure program. Eckes remarked that the program was OK and Pinnacle was moving forward with it.

236. During the late fall of 2019 and early winter of 2020 at Executive Leadership Team meetings, the topic of acquisitions of new dermatology practices was a constant theme. A recurring part of that theme was adding the SkinCure SRT Turnkey Implementation Program and the SkinCure SRT-100-Vision machine at any practice newly acquired by Pinnacle to enhance the practice's revenue stream.

237. On about February 13, 2020, Relator had another telephone conversation with Eckes when the topic of the SkinCure program came up. Relator on that occasion said to Eckes, "Are you sure that the SkinCure program is legitimate? Are you really sure? Eckes told Relator, "I sure hope it's legal."

238. *Relator engaged in covered, protected conduct each of the three or more times that he warned Eckes that the SkinCure program was not proper. Eckes and Pinnacle were placed on notice with each warning, by reasonable inference, that Relator could be considering filing a False Claims Act case against Pinnacle.*

239. *On March 13, 2020, Eckes telephoned Relator and terminated his employment with Pinnacle. This firing and other retaliatory conduct against Relator were in violation of 31 U. S. C. § 3730(h) and were the proximate result of Relator's direct warnings to Eckes that the SkinCure SRT Turnkey Implementation Program was improper.*

240. As a direct and proximate result of this unlawful and discriminatory firing and other discriminatory conduct, Relator has suffered emotional pain and mental anguish, together with lost wages, lost bonuses lost benefits and special damages associated with his efforts to obtain alternative employment, in amounts to be proven at trial.

COUNT VIII
VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

CAL. GOV'T. CODE § 12650 ET SEQ.

241. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

242. This count sets forth claims for treble damages and forfeitures under the California False Claims Act (the "California FCA").

243. Defendants, violated the California FCA in the following ways:

- a. Cal. Gov't. Code § 12651(a)(1): Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the State or its agent; and

Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.

- b. Cal. Gov't. Code § 12651(a)(2): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these false records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or its agents; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. Cal. Gov't. Code § 12651(a)(7): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State or its agents – including, but not limited to, an obligation to repay money or property defendants or their co-conspirator dermatologist had previously improperly received from the State; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agents; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agents.

244. The State of California, unaware of the fraudulent conduct and the falsity of the

claims, approved, paid, and participated in payments made by the State, including the California Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

245. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused their co-conspirator's to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

246. Defendants' knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

247. Defendants' unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going, has caused, and continues to cause, the State of California to suffer damages.

248. Accordingly, Defendants are liable, jointly and severally, for treble damages, civil penalties, and the cost of this action under the California FCA, including Cal. Gov't. Code § 12651, together with Statutory attorneys fees, interest and prejudgment interest.

COUNT IX
VIOLATION OF THE CONNECTICUT FALSE CLAIMS ACT

Conn. Gen. Stat. § 17b-301 et seq.

249. Relator re-alleges and incorporates by reference the allegations of the foregoing

paragraphs as though fully set forth herein.

250. This count sets forth claims for treble damages and forfeitures under the Connecticut False Claims Act (the “Connecticut FCA”).

251. Defendants violated the Connecticut FCA in the following ways:

- a. Conn. Gen. Stat. § 17b-301b(a)(1): Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval under a medical assistance program administered by the Department of Social Services, or its agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.
- b. Conn. Gen. Stat. § 17b-301b(a)(2): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims under a medical assistance program administered by the Department of Social Services, or its agent; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. Conn. Gen. Stat. § 17b-301b(a)(7): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State under a medical assistance program administered by

the Department of Social Services, or its agent – including an obligation to repay money or property defendants or their co-conspirator dermatologists had previously improperly received under a medical assistance program administered by the Department of Social Services; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.

- d. Conn. Gen. Stat. § 17b-301b(a)(8): Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State under a medical assistance program administered by the Department of Social Services, or its agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State under a medical assistance program administered by the Department of Social Services, or its agent.

252. The State of Connecticut, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made under a medical assistance program administered by the Department of Social Services or its agent for claims that otherwise would not have been allowed.

253. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused their co-conspirators to fail to remit funds, improperly paid under a medical assistance program administered by the Department of Social

Services or its agent. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

254. Defendants' knowing or intentional concealment and failure to report funds that were improperly received under a medical assistance program administered by the Department of Social Services for services that were not reasonable and medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

255. Defendants' unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going, has caused, and continues to cause, the State of Connecticut to suffer damages.

256. Accordingly, Defendants are liable jointly and severally for treble damages, civil penalties, and the cost of this action under Connecticut FCA, including Conn. Gen. Stat. §§ 17b-301b and 17b-301f, together with attorneys fees, interest and prejudgment interest.

COUNT X
VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

Fla. Stat. § 68.081 et seq.

257. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

258. This count sets forth claims for treble damages and forfeitures under the Florida False Claims Act (the "Florida FCA").

259. Defendants violated the Florida FCA in the following ways:

- a. Fla. Stat. § 68.082(2)(a): Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the State or its agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.
- b. Fla. Stat. § 68.082(2)(b): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or its agent; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. Fla. Stat. § 68.082(2)(g): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State or its agents – including but not limited to, an obligation to repay money or property defendants or its co-conspirators had previously improperly received from the State; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agents; and Defendants knew, or were deliberately ignorant or reckless in not

knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agents.

260. The State of Florida, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made by the State, including the State of Florida Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

261. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused its Dermagraft clients to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

262. Defendants's knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

263. Defendants's unlawful conduct occurred from on or around October 10, 2016, until the present and is continuing, and has caused, and continues to cause, the State of Florida to suffer damages.

264. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this

action under the Florida FCA, including Fla. Stat. §§ 68.082(2), 68.085, and 68.086, together with attorney's fees, interest and prejudgment interest.

COUNT XI

VIOLATION OF THE GEORGIA TAXPAYER PROTECTION FALSE CLAIMS ACT
Ga. Code Ann. § 23-3-121 et seq.

265. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

266. This count sets forth claims for treble damages and forfeitures under the Georgia Taxpayer Protection False Claims Act (the "Georgia FCA") (prior to July 1, 2012, the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-186 et seq.).

267. Defendants knowingly violated:

- a. Ga. Code Ann. § 23-3-121(a)(1): Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the State or a local government, or their agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.
- b. Ga. Code Ann. § 23-3-121(a)(2): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or a local government, or their agent; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.

- c. Ga. Code Ann. § 23-3-121(a)(7): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State or a local government, or their agent – including, but not limited to, an obligation to repay money or property defendants or their co-conspirators had previously improperly received from the State or a local government, or their agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or a local government, or their agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or a local government, or their agent.

268. The State of Georgia, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made by the State or a local government, including the State of Georgia Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

269. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused their co-conspirators to fail to remit funds,

improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

270. Defendants's knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

271. Defendants's unlawful conduct occurred from on or around October 10, 2016, until the present, and is on-going and has caused, and continues to cause, the State of Georgia to suffer damages.

272. Accordingly, Defendants are liable, jointly and severally, for treble damages, civil penalties, and the cost of this action under the Georgia FAC, including Ga. Code Ann. § 23-3-121, together with attorney's fees, interest and prejudgment interest.

COUNT XII
VIOLATION OF THE ILLINOIS FALSE CLAIMS ACT

740 Ill. Comp. Stat. § 175/1 et seq.

273. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

274. This count sets forth claims for treble damages and forfeitures under the Illinois False Claims Act (the "Illinois FCA").

275. Defendants violated the Illinois FCA in the following ways:

- a. 740 Ill. Comp. Stat. § 175/3(a)(1)(A): Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the State or its agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.
- b. 740 Ill. Comp. Stat. § 175/3(a)(1)(B): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or its agent; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. 740 Ill. Comp. Stat. § 175/3(a)(1)(G): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State or its agents – including, but not limited to an obligation by SkinCure to pay 9% sales tax and annual use taxes on about 200, SRT-100-Vision machines, which its purchased from the manufacturer, Sensus Healthcare, purchase price \$495,000, an obligation to repay money or property defendants or their co-conspirators had previously improperly received from the State; and Defendants knew, or

were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agents; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agents.

276. The State of Illinois, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid and participated in payments made by the State, including the State of Illinois Medicaid Program, or the State's agent for claims that otherwise would not have been allowed. The State of Illinois, at all material times was unaware of the purchase and true ownership by defendant, SkinCure, of about 200, SRT-100-Vision machines since October 10, 2016. Such purchases and ownership have generated sale taxes and annual use taxes together with penalties of at least \$15,000,000, which sum trebled, SkinCure presently owes the State of Illinois.

277. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused its Dermagraft clients to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

278. Defendants's knowing or intentional concealment and failure to report funds that were

improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

279. Defendants's unlawful conduct occurred from on or around October 10, 2016,, until the present and is on-going and has caused, and continues to cause, the State of Illinois to suffer damages.

280. Accordingly, Defendants is liable for treble damages, civil penalties, and the cost of this action under the Illinois FCA, including 740 Ill. Comp. Stat. §§ 175/3 and 175/4, together with attorneys fee, interest and prejudgment interest.

COUNT XIII
VIOLATION OF THE INDIANA FALSE CLAIMS
AND WHISTLEBLOWER PROTECTION ACT

Ind. Code § 5-11-5.5-1 et seq.

281. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

282. This count sets forth claims for treble damages and forfeitures under the Indiana False Claims and Whistleblower Protection Act (the "Indiana FCA").

283. Defendants violated the Indiana FCA in the following ways:

- a. Ind. Code § 5-11-5.5-2(b)(1): Defendants presented false claims to the State or its agent for payment or approval; Defendants knew, were deliberately ignorant or reckless in not knowing, or intended that these claims were false.
- b. Ind. Code § 5-11-5.5-2(b)(2): Defendants made or used false records or

statements; these false records or statements were made to obtain payment or approval of a false claim from the State or its agent; Defendants knew, were deliberately ignorant or reckless in not knowing, or intended that these records or statements were false; and Defendants intended they would be used to obtain payment or approval of a false claim from the State or its agent.

- c. Ind. Code § 5-11-5.5-2(b)(6): Defendants made or used false records or statements to avoid an obligation to pay or transmit property to the State or its agent; Defendants, were deliberately ignorant or reckless in not knowing, or intended that the records or statements were false; and Defendants knew and intended that these false records or statements would be made or used to avoid an obligation to pay or transmit property to the State or its agent.

284. The State of Indiana, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made by the State, including the State of Indiana Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

285. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused their co-conspirators to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable

or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

286. Defendants' knowing and intentional conduct constitutes an unlawful avoidance or decrease of an obligation to pay money owed to the State.

287. Defendants' unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going, and has caused, and continues to cause, the State of Indiana to suffer damages.

288. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under the Indiana FCA, including Ind. Code §§ 5-11-5.5-2 and 5-11-5.5-6, together with attorney's fees, interest and prejudgment interest.

COUNT XIV
VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS
INTEGRITY LAW

La. Rev. Stat. § 46:438.1 et seq.

289. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

290. This count sets forth claims for treble damages and forfeitures under the Louisiana Medical Assistance Programs Integrity Law (the "Louisiana FCA").

291. Defendants violated the Louisiana FCA in the following ways:

- a. La. Rev. Stat. § 46:438.3(A): Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the State or its agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.

- b. La. Rev. Stat. § 46:438.3(B): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or its agent; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. La. Rev. Stat. § 46:438.3(C): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the medical assistance programs – including an obligation to repay money or property defendants or their co-conspirators had previously improperly received from the medical assistance programs; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the medical assistance programs; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the medical assistance programs.

292. Moreover, the Louisiana False Claims Act, La. Rev. Stat. § 46:438.2A, specifically

provides that:

No person shall solicit, receive, offer or pay any remuneration, including but not limited to kickbacks, bribes, rebates, or . . . payments, directly or indirectly, overtly or covertly, in cash or in kind, for the following:

(1) In return for referring an individual to a health care provider, ... for the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

(2) In return for purchasing, leasing, or ordering, or for arranging for or recommending purchasing, leasing, or ordering, any good, supply, or service, or facility for which payment may be made, in whole or in part, under the medical assistance programs.

(3) To a recipient of goods, services, or supplies, or his representative, for which payment may be made, in whole or in part, under the medical assistance programs.

293. The State of Louisiana, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made by the State, including the State of Louisiana Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

294. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused their co-conspirators to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical

providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

295. Defendants' knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

296. Defendants's unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going and has caused, and continues to cause, the State of Louisiana to suffer damages.

297. Accordingly, Defendants are liable, jointly and severally, for treble damages, civil penalties, and the cost of this action under the Louisiana FCA, including La. Rev. Stat. § 46.438.6, together with attorneys fees, interest and prejudgment interest.

COUNT XV
VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

Mich. Comp. Laws § 400.601 et seq.

298. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

299. This count sets forth claims for treble damages and forfeitures under the Michigan Medicaid False Claim Act (the "Michigan FCA").

300. Defendants violated the Michigan FCA in the following ways:

- a. Mich. Comp. Laws § 400.607, § 7(1): Defendants made, presented, or

caused to be made or presented to an officer or employee of the State or its agent claims under the social welfare act; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.

- b. Mich. Comp. Laws § 400.607, § 7(2): Defendants made, presented, or caused to be made or presented claims under the social welfare act; Defendants knew, or were deliberately ignorant or reckless in not knowing, that the claims falsely represented that the goods or services for which the claims were made were not medically necessary in accordance with professionally accepted standards.
- c. Mich. Comp. Laws § 400.607, § 7(3): Defendants made, used, or caused to be made or used false records or statements, as alleged above; these false statements were intended to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or its agents pertaining to claims under the social welfare act.

301. The State of Michigan, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made by the State, including the State of Michigan Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

302. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused its co-conspirators to fail to remit funds, improperly

paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

303. Defendants's knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

304. Defendants' unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going, and has caused, and continues to cause, the State of Michigan to suffer damages.

305. Accordingly, Defendants are liable, jointly and severally, for damages, penalties, and costs under the Michigan FCA, including Mich. Comp. Laws §§ 400.610a and 400.612, together with attorneys fees, interest and prejudgment interest.

COUNT XVI
VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT

Minn. Stat. § 15C.01 et seq.

306. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

307. This count sets forth claims for treble damages and forfeitures under the Minnesota False Claims Act (the "Minnesota FCA").

308. Defendants violated the Minnesota FCA in the following ways:

- a. Minn. Stat. § 15C.02(a)(1): Defendants presented, or caused to be

presented, false or fraudulent claims for payment or approval to the State or its agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.

- b. Minn. Stat. § 15C.02(a)(2): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or its agent; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. Minn. Stat. § 15C.02(a)(7): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State or a political subdivision, or their agents – including an obligation to repay money or property defendants or their co-conspirators had previously improperly received from the State or a political subdivision, or their agents; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or a political subdivision, or their agents; and Defendants knew, or were deliberately ignorant or reckless in

not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or a political subdivision, or their agents.

309. The State of Minnesota, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made by the State, including the State of Minnesota Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

310. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused its Dermagraft clients to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

311. Defendants's knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

312. Defendants's unlawful conduct occurred from on or around October 16, 2016, until the present and is on-going, and has caused, and continues to cause, the State of Minnesota to suffer damages.

313. Accordingly, Defendants are liable, jointly and severally, for treble damages, civil penalties,

and the cost of this action under the Minnesota FCA, including Minn. Stat. §§ 15C.02 and 15C.12, together with attorneys fees, interest and prejudgment interest.

COUNT XVII
VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

N.Y. St. Fin. Law § 187 et seq.

314. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

315. This count sets forth claims for treble damages and forfeitures under the New York False Claims Act (the “New York FCA”).

316. Defendants violated the New York FCA in the following ways:

- a. N.Y. St. Fin. Law § 189(1)(a): Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the State or its agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.
- b. N.Y. St. Fin. Law § 189(1)(b): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or its agent; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. N.Y. St. Fin. Law § 189(1)(f): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above;

these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State or a local government, or their agents – including an obligation to repay money or property defendants or their clients had previously improperly received from the State or a local government, or their agents; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.

- d. N.Y. St. Fin. Law § 189(1)(g): Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or a local government, or their agents; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or a local government, or their agents.

317. The State of New York, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid and participated in payments made by the State or a local government, including the State of New York Medicaid Program, or their agent for claims that otherwise would not have been allowed.

318. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused their co-conspirators to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical

providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

319. Defendants's knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

320. Defendants's unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going, and has caused, and continues to cause, the State of New York to suffer damages.

321. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under the New York FCA, including N.Y. St. Fin. Law §§ 189 and 190, together with attorney's fees, interest and prejudgment interest.

COUNT XVIII
VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT

N.C. Gen. Stat. § 1-605 et seq.

322. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

323. This count sets forth claims for treble damages and forfeitures under the North Carolina False Claims Act (the "North Carolina FCA").

324. Defendants violated the North Carolina FCA in the following ways:

- a. N.C. Gen. Stat. § 1-607(a)(1): Defendants presented, or caused to be

presented, false or fraudulent claims for payment or approval to the State or its agent; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.

- b. N.C. Gen. Stat. § 1-607(a)(2): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or its agent; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. N.C. Gen. Stat. § 1-607(a)(7): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State or its agents – including an obligation to repay money or property defendants or their co-conspirators had previously improperly received from the State; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agents; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased

an obligation to pay or transmit money or property to the State or its agents.

325. The State of North Carolina, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made by the State, including the State of North Carolina Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

326. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused their co-conspirators to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

327. Defendants's knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

328. Defendants' unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going, and has caused, and continues to cause, the State of North Carolina to suffer damages.

329. Accordingly, Defendants is liable for treble damages, civil penalties, and the cost of this action under the North Carolina FCA, including N.C. Gen. Stat. §§ 1-607 and 1-610, together with

attorneys fees, interest and prejudgment interest.

COUNT XIX
VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT

Tenn. Code Ann. § 71-5-181 et seq.

330. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

331. This count sets forth claims for treble damages and forfeitures under the Tennessee Medicaid False Claims Act (the “Tennessee FCA”).

332. Defendants violated the Tennessee FCA:

- a. Tenn. Code Ann. § 71-5-182(a)(1)(A): Defendants presented, or caused to be presented, false or fraudulent claims for payment or approval to the State or its agent under the Medicaid program; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these claims were false.
- b. Tenn. Code Ann. § 71-5-182(a)(1)(B): Defendants made, used, or caused to be made or used false or fraudulent records or statements; these records or statements were material to, or intended to induce the payment of, false or fraudulent claims made to the State or its agent under the Medicaid program; Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false.
- c. Tenn. Code Ann. § 71-5-182(a)(1)(D): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged

above; these false records or statements were material to, or intended to conceal, avoid, or decrease, an obligation to pay or transmit money or property to the State or its agent relative to the medicaid program – including an obligation to repay money or property defendants or their co-conspirators had previously improperly received from the State relative to the medicaid program; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agent relative to the medicaid program; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agent relative to the medicaid program.

333. The State of Tennessee, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid and participated in payments made by the State, including the State of Tennessee Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

334. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused its Dermagraft clients to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical

providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

335. Defendants's knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

336. Defendants's unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going, and has caused, and continues to cause, the State of Tennessee to suffer damages.

337. Accordingly, Defendants is liable for treble damages, civil penalties, and the cost of this action under the Tennessee FCA, including Tenn. Code Ann. §§ 71-5-182 and 71-5-183, together with attorney's fees, interest, and prejudgment interest.

COUNT XX
VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION ACT
Tex. Hum. Res. Code Ann. § 36.001 et seq.

338. Relator re-alleges and incorporates by reference the allegations of the foregoing paragraphs as though fully set forth herein.

339. This count sets forth claims for treble damages and forfeitures under the Texas Medicaid Fraud Prevention Act (the "Texas FCA").

340. Defendants violated the Texas FCA:

- a. Tex. Hum. Res. Code Ann. § 36.002(1): Defendants made or caused to be

made false statements or misrepresentations that were material to permit people to receive benefits or payments under the Medicaid program that were not authorized or were greater than the benefits or payments that were authorized; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that the false statements or misrepresentations were material to permit people to receive benefits or payments under the Medicaid program that were not authorized or were greater than the benefits or payments that were authorized.

- b. Tex. Hum. Res. Code Ann. § 36.002(2): Defendants concealed or failed to disclose information that permitted people to receive benefits or payments under the Medicaid program that were not authorized or that were greater than the benefits that were authorized; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that the concealed information, or the information it failed to disclose, would permit people to receive benefits or payments under the Medicaid program that were not authorized or that were greater than the benefits that were authorized.
- c. Tex. Hum. Res. Code § 36.002(12): Defendants made, used, or caused to be made or used false or fraudulent records or statements, as alleged above; these false records or statements were material to an obligation to pay or transmit money or property to the State or its agent under the Medicaid program – including an obligation to repay money or property the defendants

or their co-conspirators had previously improperly received from the State; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that these records or statements were false. Defendants concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agent under the Medicaid program; and Defendants knew, or were deliberately ignorant or reckless in not knowing, that their conduct concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the State or its agent under the Medicaid program.

341. The State of Texas, unaware of the fraudulent course of conduct and the falsity of these claims, approved, paid, and participated in payments made by the State, including the State of Texas Medicaid Program, or the State's agent for claims that otherwise would not have been allowed.

342. Through the acts described above, Defendants intentionally or knowingly failed to remit funds, or intentionally or knowingly caused their co-conspirators to fail to remit funds, improperly paid by Government Payors. Defendants intentionally and improperly caused medical providers to charge Government Payors for products and/or procedures that were not reasonable or medically necessary, that were in some instances tainted by kickbacks, and otherwise not properly reimbursable.

343. Defendants's knowing or intentional concealment and failure to report funds that were improperly received from Government Payors for services that were not reasonable or

medically necessary and tainted by kickbacks and otherwise not properly reimbursable constitute an unlawful avoidance or decrease of an obligation to pay money owed to the State.

344. Defendants's unlawful conduct occurred from on or around October 10, 2016, until the present and is on-going, and has caused, and is causing, the State of Texas to suffer damages.

345. Accordingly, Defendants are liable for treble damages, civil penalties, and the cost of this action under the Texas FCA, including Hum. Res. Code § 36.007, together with attorney's fees, interest and prejudgment interest.

PRAYERS FOR RELIEF

WHEREFORE, Relator, Creger, on behalf of the United States and the Plaintiff States, and on his own behalf, requests that this Court enter an order:

- a. That Defendants violated the Federal and State False Claims Acts;
- b. That Defendants pay an amount equal to three times the amount of damages the United States and the Plaintiff States have sustained because of Defendants' actions, plus a civil penalty against Defendants of not less than \$11,665 and not more than \$23,331 for each violation of the Federal and State False Claims Acts;
- c. That Defendants cease and desist from violating the Federal and State FCAs;
- d. That Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to the Federal and State FCAs;
- e. That Relator be awarded the maximum amount allowed as a relator share pursuant to 31 U.S.C. § 3730(d) and comparable provisions of the State False Claims Acts; and
- f. That the United States, the Plaintiff States and Relator be granted all such other and

further relief as the Court deems just and proper.

RELATOR DEMANDS TRIAL BY JURY ON ALL COUNTS.

Respectfully submitted,

RELATOR DANIEL W. CREGER

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Attorneys for Relator

STATE OF TENNESSEE)

COUNTY OF DAVIDSON)

VERIFICATION

WILLIAMSON

Appeared before me the undersigned Notary Public, Daniel W. Creger, who, after being placed under oath, did depose and say the following:

My name is Daniel W. Creger and I am over the age of twenty-one (21) years, of sound mind and not under the influence of any drugs or medications. I have reviewed the factual assertions and statements contained in the foregoing Verified Complaint and each Exhibit attached thereto. The statements and information contained in the said Verified Complaint and Exhibits are true and correct based upon either my firsthand knowledge or the contents of the said Exhibits. I make this Disclosure Statement voluntarily as my own free act and deed and further acknowledge that I have not been influenced or coerced to do so.


Daniel W. Creger

Sworn to and subscribed before me
this 11 day of July, 2020

SEPTEMBER

Notary Public
My Commission Expires:

NOV 19, 2023

(SEAL)

